UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re SAGE THERAPEUTICS, INC. SECURITIES LITIGATION	:	Civil Action No. 1:24-cv-06511-JAV
	:	CLASS ACTION
	:	DEMAND FOR JURY TRIAL

AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

Lead Plaintiffs Steamfitters Local 449 Pension & Retirement Security Funds and Trust of the Retirement System of the UPR (collectively, "Plaintiffs"), by and through the undersigned counsel, allege the following based on personal knowledge as to themselves and their own acts, and for all other allegations based upon the investigation undertaken by Lead Counsel, which included, but was not limited to, reviewing and analyzing: (a) public filings made by Sage Therapeutics, Inc. ("Sage" or the "Company") with the U.S. Securities and Exchange Commission ("SEC"); (b) press releases and other public statements by Sage and other Defendants named herein; (c) securities and financial analysts' research reports and media and news reports on Sage, as well as earnings and other investor and analyst conference calls; (d) reports on the U.S. Food and Drug Administration's ("FDA") New Drug Application ("NDA") approval process and FDA guidance; and (e) literature on the clinical trials associated with the pharmaceuticals that Sage had under development during the Class Period (defined below). Plaintiffs believe that substantial additional evidentiary support exists for the allegations set forth herein, which Plaintiffs will uncover and develop after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This putative securities class action is brought on behalf of all persons and entities, except those excluded in the definition of the Class below, who purchased or otherwise acquired Sage securities between April 12, 2021 and July 23, 2024, inclusive ("Class Period"), asserting violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. §§78j(b) and 78t(a), respectively, and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. §240.10b-5, against Sage and several of its current or former executives, including President, Chief Executive Officer ("CEO"), and director Barry E. Greene ("Greene") (collectively, "Individual Defendants," and with Sage, "Defendants").

2. Sage is a biopharmaceutical company that develops and commercializes brain health medicines. This action involves Defendants' fraudulent scheme to conceal adverse information and substantial risks associated with Sage's development of three pharmaceuticals, described below, during the Class Period: zuranolone (SAGE-217/BIIB125), a flagship drug, then under development in collaboration with affiliates of Biogen Inc. (together, "Biogen"), whose most lucrative potential application was to treat major depressive disorder ("MDD"); SAGE-718 (dalzanemdor), for the treatment of certain cognitive disorders and diseases; and SAGE-324 (BIIB124), under development with Biogen, for the treatment of essential tremor.

3. During the Class Period, Defendants actively promoted zuranolone as an effective treatment for both postpartum depression ("PPD") and MDD, ultimately causing Sage to submit a rolling NDA to the FDA for both indications. In favorable statements to investors and securities analysts throughout the Class Period, they expressed unrestrained confidence in the NDA process for both applications, invoking positive communications with the FDA as support for their optimism that FDA approval for zuranolone was forthcoming for the treatment of PPD and MDD.

4. Defendants' positive statements continued even though a competing oral treatment, Auvelity (dextromethorphan and bupropion)—under development by Axsome Therapeutics, Inc. ("Axsome") to treat MDD—was nearing FDA approval, granted in August 2022. Like zuranolone, Auvelity was promoted as a fast-acting, oral pharmaceutical with durable efficacy and manageable side effects no worse than drowsiness, capable of statistically significant improvements in depressive symptoms for at least six weeks. Yet Defendants omitted nearly all mention of Auvelity and the risk that the market for zuranolone would exponentially contract if Auvelity received approval. Nor did they caution that FDA approval of Auvelity would materially reduce zuranolone's chances for FDA approval, because Auvelity—an objectively safer and more effective drug—already addressed the unmet need in MDD that Sage sought to address with zuranolone.

5. By the end of the Class Period, investors learned that the FDA had denied approval of zuranolone for the treatment of MDD because it lacked long-term efficacy and was no better than a placebo after only weeks—a drug profile inconsistent with FDA guidance from 2018 for developing a lasting and effective MDD treatment. Investors also learned that in approving zuranolone for PPD but not MDD, the FDA emphasized that clinical testing seemed to correlate zuranolone with an increased incidence of suicidal ideation and behavior in MDD patients that was not present for PPD patients. Investors were also shocked to learn that Sage abandoned developing SAGE-718 and SAGE-324 due to adverse clinical trials, resulting in Biogen's decision to terminate its collaboration and license agreement with Sage for the development of SAGE-324.

6. As alleged herein, Defendants knowingly or recklessly misrepresented and omitted material, adverse information about these drugs in their Class Period representations, and Sage's stock price suffered as a result when the truth emerged. Given that Sage generated limited revenue from the sale of the only drug it had commercialized—Zulresso, which received FDA approval in 2019, shortly before the Class Period began—Defendants were motivated to engage in the fraud to artificially inflate and maintain Sage's stock price to allow the Company to sell securities on an as-needed basis to fund operations.

7. In fact, as part of Sage's arrangement with Biogen, Biogen made an upfront payment of $850 million and purchased $650 million in Sage common stock—10.7% of its then-outstanding shares—at a cumulative 40% premium. Although this transaction preceded the Class Period, it was part of the same fraudulent scheme that Defendants perpetrated during the Class Period to maintain Sage's artificially inflated stock price, which was essential to the Company's continued existence. Without Biogen's financial support (secured on the basis of false pretenses), the Company would not have had enough cash on hand during the Class Period to finance operations or drug development, including clinical trials for zuranolone, SAGE-324, and SAGE-718.

8. The exposure of the fraud decimated Sage's stock price and required several rounds of cost cuts—including eliminating about half of the Company's research and development ("R&D") spending—as well as two rounds of workforce restructuring that resulted in large-scale terminations and management reorganization. The Company's precarious financial condition directly resulted in Biogen's opportunistic January 2025 offer to acquire the outstanding stock it did not already own for $469 million—a significant discount, well below Sage's intrinsic value and the amount that Biogen paid for just 10% of Sage in 2020. As Biogen stated, "a 'broader relationship' between the two companies is no longer possible due to Sage's research setbacks and . . . financial difficulties." That public overture led to expedited litigation in the Delaware Court of Chancery, which Sage initiated to prevent Biogen's takeover. As of this date, the Delaware litigation remains pending.

9. This action seeks to recover monetary damages for Sage investors who were harmed by Defendants' fraudulent scheme during the Class Period.

II. JURISDICTION AND VENUE

10. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. §240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and Section 27 of the Exchange Act, 15 U.S.C. §78aa, and personal jurisdiction exists over each Defendant.

11. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. §78aa, and 28 U.S.C. §1391(b), because the Company conducts a substantial amount of business in this District and a significant portion of the damages due to Defendants' misconduct were suffered in this District. Additionally, at all relevant times, Sage's common stock traded on the Nasdaq Global Market ("NASDAQ"), and continues to trade on the NASDAQ, which is located in this District.

12. In connection with the acts, conduct, and other wrongs alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, U.S. mails, interstate telephone communications, and facilities of the national securities markets, and the situs of this action accordingly lies within this District.

III. PARTIES

A. Plaintiffs

13. Plaintiffs are institutional pension funds. As set forth in their Certifications, filed on October 28, 2024 (ECF No. 19-2), Plaintiffs purchased Sage common stock during the Class Period and were damaged thereby.

B. Defendants

1. Sage

14. Founded in April 2010, Defendant Sage is a Delaware corporation with principal executive offices located in Cambridge, Massachusetts. Sage is a biopharmaceutical company that designs and develops drugs to treat diseases and disorders of the brain, where, it claims, patient populations are easily identified, clinical endpoints are well-defined, and development pathways are feasible. In its entire history, Sage had commercialized and brought to market only one drug, which generated limited revenue: Zulresso (brexanolone), an intravenous treatment for adult PPD, which the FDA approved in March 2019 and Sage launched in the U.S. in June 2019.

15. Sage has historically experienced substantial net losses each year since its formation, in 2010. In fact, although Sage received $1 billion in upfront payments under its collaborations with Biogen and Japan-based Shionogi & Co., Ltd. ("Shionogi"), it recorded net income of $606.1 million for the year ended December 31, 2020 based on revenue recognized from its collaboration and license agreement with Biogen. Given its limited revenue-generating ability and consistent net losses associated with absorbing the costs of developing its pharmaceuticals, Sage has historically

funded operations with securities sales, generating aggregate net proceeds of $2.8 billion from such transactions from 2010 onward.

16. During the Class Period, Sage had over 59 million shares of common stock issued and outstanding. At all relevant times, the Company's common stock was publicly traded on the NASDAQ under the ticker symbol "SAGE."

2. The Individual Defendants

17. Defendant Greene has served as Sage's CEO and President since December 2020 and as a member of its Board of Directors since October 2020. As alleged herein, he was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period. He also signed certain SEC filings.

18. Defendant Kimi Iguchi ("Iguchi") was Sage's Chief Financial Officer ("CFO") and Treasurer from March 2013 until October 2024, when Sage implemented a "strategic reorganization" that resulted in the termination of 33% of the total workforce and four other senior executives. As alleged herein, she was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period. She also signed certain SEC filings.

19. Defendant Al Robichaud ("Robichaud") was Chief Scientific Officer from Sage's founding in November 2011 until his departure, announced in August 2023 when Sage implemented its first "strategic reorganization"—resulting in the termination of 40% of its total workforce and the departure or repositioning of other senior executives. Upon his departure, he remained a scientific consultant and member of Sage's Medical Chemistry and Pre-Clinical Scientific Advisory Boards. As alleged herein, he was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period.

20. Defendant Christopher Benecchi ("Benecchi") was Chief Commercial Officer from September 2021 until October 2024, when he assumed the role of Chief Operating Officer in connection with Sage's second "strategic reorganization." As alleged herein, he was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period.

21. Defendant Jim Doherty ("Doherty") is a founding member of Sage and served in various roles, including Senior Vice President of Research (until 2017), Chief Research Officer (until 2021), and Chief Development Officer, until his departure, announced in August 2023 when Sage implemented its second "strategic reorganization." On behalf of Sage, Doherty co-authored research papers on certain drugs at issue in this action. As alleged herein, he was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period.

22. Defendant Stephen J. Kanes ("Kanes") was Sage's Chief Medical Officer from July 2013 until about November 2021, when he resigned. On behalf of Sage, Kanes co-authored research papers on certain drugs at issue in this action. As alleged herein, he was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period.

23. Defendant Laura Gault ("Gault") became Sage's Chief Medical Officer in or about November 2022 and remains in this position. As alleged herein, she was responsible for authoring, issuing, and approving the dissemination of certain materially false and misleading statements and omissions of fact during the Class Period.

IV. BACKGROUND

A. Sage Generated Limited Revenue from a Single Drug and Historically Financed Its Business with Proceeds from Securities Transactions

24. By the start of the Class Period, Sage had commercialized and brought to market only one drug: Zulresso (brexanolone)—administered intravenously over 60 hours (2.5 days) in a certified and medically-supervised healthcare setting—for treating PPD in adult women, which the FDA approved in March 2019 and Sage launched in the U.S. in June 2019. Administering Zulresso also required a risk evaluation and mitigation strategy program for patients due to excessive sedation and sudden loss of consciousness. Given the required medical setting and stringent protocols associated with administering Zulresso, as well as its $34,000-per-course cost and narrow application, Sage has historically generated only limited revenue from the drug. In 2023, for example, net revenue from sales of Zulresso were only $10.5 million.

25. In its Form 10-K for fiscal year ended December 31, 2023, filed with the SEC on February 14, 2024 ("2023 Form 10-K"), Sage described many of the complications that limited the Company's ability to generate revenue from Zulresso, conceding elsewhere that it "may not," in fact, "generate meaningful revenue or revenue" from the sale of that drug (or others) "at the levels or on the timing necessary to support [its] investment and goals":

> Our current commercial operations for ZULRESSO are limited to account management focused on geographies that have existing, active ZULRESSO treatment sites. We expect that the commercial availability of ZURZUVAE for women with PPD, our limited commercial efforts for ZULRESSO, and barriers to treatment with ZULRESSO will continue to substantially limit the revenue opportunity for ZULRESSO and the number of healthcare settings that are or become treatment sites for ZULRESSO.

26. As a result, Sage only began generating revenue in the second quarter of 2019, when Zulresso received FDA approval and became commercially available. Until then, as the 2023 Form 10-K recites, Sage funded its operations primarily through proceeds from sales of common stock and

other securities transactions. In fact, from its inception in 2010 through December 31, 2023, Sage received aggregate net proceeds of $2.8 billion from these transactions, but incurred net losses each year with just one exception: net income of $606.1 million for the year ended December 31, 2020, reflecting revenue recognized under a collaboration and license agreement with Biogen, which did not involve the sale of any products to the public.

27. Given Zulresso's limited commercial market, it was exceedingly important for Sage to develop pharmaceuticals with substantial commercial prospects. One way it sought to do so was by leveraging its relationship with Biogen, including the collaboration and license agreement, and a separate stock purchase agreement, both entered into on November 27, 2020. This arrangement with Biogen resulted in a total cash infusion of $1.525 billion, which Biogen was obligated to pay.

28. The collaboration and license agreement, to which Biogen MA Inc. and Biogen International GmbH were parties, related to jointly developing zuranolone (SAGE-217) and SAGE-324 for sale in the U.S. Under that agreement, which became effective in December 2020, Biogen agreed to an upfront payment of $875 million, and regulatory and commercial milestone payments, to Sage, and Biogen and Sage agreed to equally split profits and losses. Biogen also obtained the right to sell zuranolone and SAGE-324 (and certain derivatives thereof) outside of the U.S., except in Japan, South Korea, and Taiwan (where Shionogi had the right to sell zuranolone under a June 12, 2018 agreement with Sage).

29. As part of this arrangement, Biogen MA Inc. agreed to purchase $650 million of Sage common stock, representing 10.7% of the Company's then-outstanding shares. The stock purchase agreement obligated Sage to issue and sell 6,241,473 shares of stock to Biogen at a price of $104.14, reflecting a premium of 40% over the volume-weighted average share price for the 30 days ending on the day prior to the agreement (*i.e.*, November 26, 2020). The sale closed on December 31, 2020. The stock purchase agreement also imposed a standstill provision, lock-up restrictions, and a voting

agreement on Biogen, limiting Biogen's ability to sell or transfer Sage shares for at least 18 months, purchase additional Sage stock, or influence Sage's management or operations.

30. As noted, Sage generated an aggregate of $2.8 billion from securities transactions, including the sale to Biogen. These transactions included selling redeemable convertible preferred stock before its July 2014 initial public offering ("IPO"), issuing convertible notes, and selling common stock in its IPO and follow-on public offerings. The inability to generate revenue from the commercialization of its pharmaceuticals prompted Sage to disclose in its Class Period SEC filings that it would continue to engage in securities transactions to finance its operations:

> Until such time that we can generate significant revenue on a sustained basis from product sales and/or from collaborations, if ever, we expect to finance our operations primarily through a combination of revenue, equity or debt financings and other sources, including our collaborations with Biogen and Shionogi and potential future collaborations.

31. Additionally, during the Class Period, Sage filed a shelf-registration statement so it could issue shares periodically without the expense or delay inherently involved in filing individual registration statements. A registration statement, filed on December 16, 2021 and declared effective on December 17, 2021, allowed the Company to tap the public markets at will—presumably, at opportunistic times—to generate revenue through the planned sale of securities, including common stock, preferred stock, debt securities, warrants, and units.

32. Subsequently, on November 7, 2023, Sage entered into a sales agreement with Cowen and Company, LLC ("Cowen") as sales agent, with respect to an "at the market offering" program pursuant to which the Company could offer and sell shares of common stock, having an aggregate offering price of up to $250 million, from time to time through Cowen. On that date, Sage also filed a prospectus supplement to the December 2021 shelf-registration statement, expressing the intention of engaging in additional stock sales to generate proceeds when desired.

33. Given Sage's dependency on securities transactions to fund its operations, including its substantial research and development costs, increasing and maintaining Sage's stock price and perceived value was absolutely essential to the Company's business and survival.

B. Sage Publicly Emphasized the Multibillion-Dollar Opportunity to Treat MDD in Adults as the Most Lucrative Market for Zuranolone

34. From the beginning, Sage emphasized the treatment of MDD as zuranolone's most lucrative market opportunity and referenced communications with the FDA to instill confidence in zuranolone's path to FDA approval. On March 18, 2020, a year before the start of the Class Period, Sage issued a press release announcing the "development plan" for zuranolone after a Breakthrough Therapy guidance meeting with the FDA. According to Sage, there were three potential pathways to FDA approval, for three distinct indications (one in PPD, and two in MDD):

a. an oral therapy in women with PPD, requiring "one additional positive pivotal trial, along with data from previously completed studies";

b. an acute rapid response therapy in patients with MDD when co-initiated with new standard antidepressant therapy, which required "one additional positive treatment study, along with data from previously completed studies"; and

c. an episodic therapy for MDD, which required "one additional positive pivotal trial, along with previously completed acute treatment studies and long-term safety data[.]"

35. The press release quoted Sage's then-President and CEO Jeff Jonas, M.D., who said: "Following FDA guidance, Sage has several potential pathways to bring zuranolone to patients," "with two pathways that would represent unique indications that we believe we can progress quickly and efficiently, while in tandem we pursue our original approach to develop zuranolone for the episodic treatment of depression . . . ." As the release indicated, "[f]ollowing discussions with the FDA," Sage planned to "initiate three new short-term clinical studies in 2020," while expecting to

report topline data in 2020 from the SHORELINE study, as well as "to enroll a new cohort of patients with MDD," but paused enrollment in REDWOOD (MDD-302) and RAINFOREST (MDD-304) studies in the fourth quarter of 2019.

36. While the market for antidepressants as a whole is large, the market for treating PPD is relatively small. The global market for antidepressants in 2020 was $14.93 billion, projected to grow to $18.29 billion by 2027. By and large, however, the growing demand for antidepressants is fueled by a rise in MDD. According to the Anxiety & Depression Association of America, about 14.8 million adults in the U.S. experienced at least one major depressive episode in 2020 alone. As Chief Medical Officer Kanes recognized in comments on August 3, 2021, "with greater than 30 drugs approved in the United States for MDD, there are still upwards of 19 million people a year" who experience "a depressive episode" "that's relatively straightforward to treat, [so] the unmet need is enormous." According to the World Health Organization, depression affects 280 million people worldwide. In comments on January 12, 2021, Greene emphasized that "nearly 800 million people globally" suffered from "mental health disorders," noting that a "still staggering" subset—"[n]early 200 million people a year"—experienced a "major depressive episode."

37. The global COVID-19 pandemic increased the need for effective medicines designed to treat MDD, and the key to prevent recurrent episodes is the long-term efficacy of treatment. As Greene indicated at a November 15, 2021 conference: "Depression is rising at an ever-increasing rate. It was rising quickly with the COVID pandemic into a fourfold increase from pre-pandemic level. So if we had drugs that worked effectively, that would not be happening. We would not see dramatic rising of cases." As he recognized, describing the appeal of a fast-acting and long-lasting MDD treatment: "People with depression have higher case[s] of COVID because it messes with their immune system. So medically, getting someone better, fast and keeping them better, medically is the right thing to do."

38. The PPD market, by contrast, is significantly smaller in size because patients consist of a cross-section of women after pregnancy, who experience depressive symptoms associated with the stressors related thereto. One report estimated the size of the PPD market at about $800 million in 2021. But vexing complications prevent developing and administering PPD drugs. According to an April 10, 2024 article from *Biopharma Dive*, entitled "New postpartum depression drugs are here. Diagnosis, treatment hurdles still stand in the way," clinical trials often exclude pregnant women out of fear for harming the fetus, enrolling postpartum women in trials is difficult, and the window of time to test a therapy is small.

39. In August 3, 2021 comments, Sage's Chief Medical Officer, Kanes, acknowledged these testing difficulties, noting that for zuranolone, Sage was "not enrolling patients in [an ongoing PPD] study, despite when their diagnosis was made until a full month after the delivery," to avoid "medicalizing . . . normal changes in mood immediately after delivery." Before the FDA approved zuranolone to treat PPD, Sage's drug Zulresso was the only specific PPD treatment, but access was complicated and limited by dose administration (requiring infusion over 60 hours in a healthcare facility) and a risk evaluation and mitigation strategy program due to excessive sedation and sudden loss of consciousness. These issues, coupled with the high cost of treatments, pose unique problems that preclude the large-scale commercialization and sale of PPD pharmaceuticals in the U.S.

40. For all of these reasons, the media, industry commentators, and securities analysts following Sage recognized that MDD represented the most promising market for zuranolone. This was also a predominant reason why Biogen agreed in November 2020 to collaborate with Sage on developing the drug: a widely-prescribed indication for treating MDD was extremely lucrative. On November 27, 2020, *Reuters* in fact reported that the purpose of Sage's agreement with Biogen was "to jointly develop and sell a treatment for major depressive disorder"—neglecting to mention the drug's proposed indication also for PPD.

C. Due to the Chronic Nature of MDD and a Lack of Effective Treatments, Pharmaceutical Developers Knew that the FDA Would Likely Approve MDD Drugs Only with Long-Term Efficacy and Durability of Effect

41. MDD is a troubling mental health condition that afflicts millions of people globally. Symptoms range from general malaise and mood swings to suicidal ideation and behavior. It is a chronic illness; those afflicted with the disease must live with it for extensively long periods, if not their entire lives. Depressive episodes often recur. Reportedly, the recurrence rate is 50% after the first episode, 70% after the second, and 90% after the third. The chronic and recurrent nature of MDD complicate treatment solutions.

42. As Sage's CEO Greene observed on an August 3, 2021 conference call, the "[c]urrent standard of care treatment for MDD can be slow for patients to experience [any] response," "with most patients staying on some form of chronic treatment for at least 2 years . . . ." In reviewing the NDA for zuranolone, the FDA noted that "[p]atients starting antidepressants may experience some improvement within 1 or 2 weeks," but recognized that "many patients require 8 to 12 weeks of treatment to experience substantial improvement or remission." The FDA indicated that "[t]here are numerous options for the treatment of MDD" and that "[a]ntidepressants are typically intended for chronic use," but noted that "efficacy is suboptimal and approximately one-third of patients would not respond to several trials with different antidepressants." As the FDA observed: "an unmet need remains for more rapid and more effective treatments for both MDD and PPD."

43. Also complicating treatment is the subjective nature of the disease. Because MDD affects mental health, it is difficult for a third party—including trained clinicians—to ascertain the severity of the condition for a particular person. No objective test is available to diagnose MDD. Instead, clinicians use various means of evaluating a patient's subjective assessments of the severity and symptoms of MDD. Most widely used are the Hamilton Depression Rating Scale ("HAM-D"), which consists of 17 items used to assess a patient's feelings and symptoms, and the Montgomery-

Asberg Depression Rating Scale ("MADRS"), which classifies and assigns a numerical value to a patient's depressive symptoms. Both scales derive information from clinical interviews of patients, and both have their own advantages and limitations. For example:

a. HAM-D is not a diagnostic instrument, but is often used to monitor patients already diagnosed with depression. Although the scale covers 21 items, the score is generated based on the first 17, which are measured on 5-point or 3-point scales. The scale considers a broad range of symptoms, including mood, insomnia, anxiety, weight loss, and suicidal tendencies. Some have criticized HAM-D for emphasizing certain symptoms over others, which can skew perceptions of treatment effectiveness. It is often used in clinical trials because it is comprehensive, but its length and complexity make it time-consuming and sometimes challenging to administer.

b. MADRS does not assess all of the elements that HAM-D does, such as sexual function or depersonalization. The scale covers 10 items, each rated on 7-point scales. MADRS is regarded as an adaptation of HAM-D and is sensitive to change over time. The scale focuses on core depressive symptoms, such as sadness and pessimism. It is generally quicker to administer.

44. To assess patients' depressive symptoms, clinicians also use other established tests, including the 36-Item Short Form Survey ("SF-36") and the Columbia-Suicide Severity Rating Scale ("C-SSRS"). SF-36 is a patient survey involving 36 questions that cover eight quality-of-life issues, ranging from limitations in physical or social activities as a result of depressive symptoms to overall health. C-SSRS is a questionnaire designed to promptly assess suicide risk, including the extent and immediacy of the risk. The test, which someone with no specialized clinical training can administer, is meant to evaluate the full range of suicidal thoughts (known as suicidal ideation) and behaviors, such as acts in furtherance of committing suicide.

45. Because MDD is long-lasting, recurrent, episodic, and evolving in patients, the FDA issued guidance for the development of pharmaceuticals intended to treat MDD. In September 1977,

the FDA issued the *Guidelines for the Clinical Evaluation of Antidepressant Drugs*. More recently, in June 2018, the Division of Psychiatry Products in the Center for Drug Evaluation and Research at the FDA issued guidance entitled *Major Depressive Disorder: Developing Drugs for Treatment*, which revised and replaced the September 1977 guidelines and remains current. The FDA's current guidance emphasizes the importance of a long-lasting and effective treatment, known as durability.

46. In outlining "specific efficacy trial considerations," the FDA instructed drug sponsors to examine the timing of the effect in developing short-term treatment for a depressive episode. As the FDA explained, "[e]fficacy generally should be demonstrated within 1 week for a rapid-acting antidepressant," but "[d]urability of [the] effect beyond the initial response should be characterized." According to the FDA's guidance: "To demonstrate both early onset of action and durability of effect, a primary efficacy endpoint early in the course of treatment would be chosen, with continued observation of drug-placebo differences over time."

47. Because depression often recurs after short-term treatment, the FDA also emphasized the importance of "maintenance treatment," explaining: "Because depression usually is a cyclical disease, maintenance studies of conventional antidepressants are actually assessments of the ability of the drug to reduce the rate of recurrence of depression." Indeed, as the FDA noted in addressing "long-term safety data," "[c]onventional drugs for treatment of MDD are often taken long-term (defined as continuous or intermittent use for at least 6 months), given that MDD is a chronic condition requiring ongoing management to reduce the rate of recurrence." As the FDA indicated, "most recurrences are delayed."

48. Thus, "[f]or rapid-acting antidepressants, there is interest in whether the rapid effect does in fact persist for the episode treated." For this reason, FDA guidance expresses the specific need for MDD treatments with longer-lasting effects, noting: "The FDA is interested in studies that

explore whether treatment response can be maintained with a lower dose of the drug than is needed for short-term efficacy, and whether a lower dose may improve tolerability."

49. Given the difficulty in designing appropriate clinical trials for MDD pharmaceuticals, "[h]igh placebo response rates and small magnitude of treatment effect (relative to placebo) are of concern in most conventional antidepressant trials, which makes defining the active control effect and choosing a noninferiority margin difficult." At the same time, because "high placebo response and dropout rates" are "commonly observed, sponsors should consider these factors in sample size calculations to ensure that the trial has sufficient statistical power to detect the anticipated treatment effect." Thus, while the FDA acknowledged that placebo rates may be high in antidepressant trials, they remain an important data point and provide necessary context in evaluating and assessing the efficacy of antidepressants under development.

50. The FDA guidance also noted the difficulty associated with studying the efficacy of antidepressants on pregnant woman, confirming that "pregnant women typically are excluded from antidepressant trials . . . ." As a result, the FDA opined that "[s]ponsors should collect safety data in women who are inadvertently exposed in pregnancy during drug development trials and in pregnant women who use these drugs in the postmarketing setting." These assessments confirmed the less-than-optimal trial protocols available to test antidepressants on this population of potential patients, while also implicitly recognizing the relatively smaller market for treating depression in women who are pregnant or have given birth.

51. Accordingly, the FDA emphasized the importance for drug sponsors to focus on the long-term efficacy of pharmaceuticals under development for the treatment of MDD, given that the condition is chronic and MDD episodes typically recur within 6 months. The FDA also expressed the importance of developing pharmaceuticals capable of managing the condition and preventing a

recurrence, emphasizing the durability of effect and efficacy of drug candidates at a longer endpoint while instructing sponsors to monitor drug-placebo differences over time.

52. Based on these considerations, pharmaceutical developers and clinicians understood that the FDA would likely not approve short-term treatments for MDD, and that the FDA favored treatments with long-lasting efficacy and durability. As discussed above, in evaluating the NDA for zuranolone, the FDA recognized "an unmet need . . . for more rapid and more effective treatments" for MDD and PPD. In developing zuranolone, Defendants keenly understood the FDA's guidance and concerns, and, as they represented during the Class Period, met with FDA officials regularly, both before and after submitting the NDA.

53. As explained below, in requesting FDA approval, Sage promoted zuranolone as a 14-day oral treatment with rapid and durable effects despite the short period of dosing. However, as the FDA revealed in approving zuranolone for treating PPD but not MDD, the FDA communicated the unique requirements for approval consistently in meetings before and during the Class Period:

> Prior to NDA submission, the Agency interacted with the Applicant in numerous Type B and C meetings on May 15, 2018; December 13, 2018; May 15, 2019; January 30, 2020; February 4, 2021; June 15, 2021; September 13, 2021; and January 19, 2022. At these meetings, the Agency communicated that in the context of the proposed novel 14-day treatment paradigm, [REDACTED] the Applicant would need (1) to demonstrate durability of effect in addition to the acute 14-day treatment effect, (2) to characterize [REDACTED] and (3) to ensure a long-term safety database comprised of an adequate number of subjects [REDACTED] at the highest dose proposed for marketing (i.e., 50 mg).

54. Evidently, Sage satisfied the FDA approval criteria in treating PPD with zuranolone, but not MDD. As the FDA revealed in approving zuranolone's indication for the treatment of PPD, the FDA also expressed serious concern regarding the correlation between zuranolone and increased incidence of suicidal ideation and behavior in MDD patients during clinical testing—correlation that was not present, at all, in PPD patients during testing. Securities analysts expressed shock at this revelation, underscoring the unique information—and implications of that information—Defendants

concealed from the public during the Class Period, all of which eventually (foreseeably) contributed to the FDA's denial of approval for zuranolone in the treatment of MDD.

55. By contrast, Auvelity (AXS-05) received FDA approval for the treatment of MDD in August 2022. As the Forms 10-Q and 10-K during the Class Period confirm, the Company viewed Auvelity as a potential competitor to zuranolone. In truth, Auvelity was much more than that: it was also a fast-acting drug with durable efficacy and relatively minor side effects that exhibited higher levels of statistical significance over longer periods. With knowledge that Auvelity received FDA approval in August 2022, Defendants surely understood and appreciated the risks to zuranolone's prospects for approval—because the FDA was unlikely to approve any other drug for the treatment of MDD, unless it was objectively more durable and safer than Auvelity. Zuranolone was neither.

D. Before the Class Period Begins, Sage Conducts and Completes Clinical Trials on Zuranolone, SAGE-718, and SAGE-324, and Induces Biogen to Make a Substantial Upfront Payment and Stock Purchase

56. In June 2018, Sage entered into a strategic collaboration with Shionogi for the clinical development and commercialization of zuranolone for the treatment of MDD and other indications in Japan, South Korea, and Taiwan. The relationship expanded in October 2018. In connection with that arrangement, Sage agreed to license zuranolone material to Shionogi in exchange for an upfront fee of $90 million, and Shionogi assumed responsibility for clinical development, regulatory filings, and commercialization and manufacturing of zuranolone in those non-U.S. territories.

57. In November 2020, Sage and Biogen agreed to collaborate on developing zuranolone for the treatment of MDD and PPD in the U.S., while Biogen secured the right to commercialize the drug for sale in other territories in which Shionogi did not operate. Sage and Biogen also similarly agreed to jointly develop SAGE-324, and Sage planned to independently develop SAGE-718. All of these pharmaceuticals were under development before and during the Class Period to treat central nervous system disorders tied to mental health, such as varying forms of depression. For example:

a. Zuranolone is a neuroactive steroid that is a positive allosteric modulator of $GABA_A$ receptors. The GABA receptor family is a major inhibitory neurotransmitter in the central nervous system, mediating neurologic and bodily function via activation of $GABA_A$ receptors. Sage intended to develop zuranolone for the treatment of MDD and PPD and evaluated the drug in the LANDSCAPE and NEST clinical development programs.

i. The LANDSCAPE program included five clinical studies of MDD: MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL. Shionogi also completed a Phase 2 study of zuranolone in Japan for people with MDD.

ii. The NEST program included two placebo-controlled studies for PPD: ROBIN and SKYLARK.

b. SAGE-324 is also a positive allosteric modulator of $GABA_A$ receptors, but intended for chronic oral dosing. Sage intended to develop SAGE-324 for the treatment of essential tremor and other neurological conditions, including epilepsy and Parkinson's Disease. According to Sage, essential tremor affects 6.4 million people in the U.S. alone, and more than 50% of patients experience suboptimal response with current standard of care treatments.

c. In contrast to zuranolone and SAGE-324, SAGE-718 is an oxysterol-based positive allosteric modulator of the NMDA receptor of the glutamate receptor system. NMDA-type receptors are a major excitatory receptor system in the central nervous system. Sage intended to develop SAGE-718 for the treatment of cognitive impairment associated with various diseases, such as Huntington's, Parkinson's, and Alzheimer's Diseases.

58. By the start of the Class Period in April 2021, clinical trials were underway for all three drugs and some had been completed. For zuranolone, Sage was conducting three Phase 3 placebo-controlled trials—the WATERFALL and CORAL studies in MDD, and the SKYLARK study in PPD—and an open-label Phase 3 trial, the SHORELINE study, in MDD. In December

2019, Sage completed the MOUNTAIN study for zuranolone—a Phase 3 trial in MDD—that did not meet its primary endpoint.

59. For SAGE-324, Sage was conducting the KINETIC study, a placebo-controlled Phase 2 trial designed to evaluate safety and efficacy for essential tremor in adults. In April 2021, Sage reported that this study met its primary endpoint. As a result, Sage planned to initiate the KINETIC 2 study—a Phase 2b placebo-controlled dose-ranging trial—in late-2021.

60. For SAGE-718, Sage was conducting two Phase 2a open-label trials: PARADIGM, for patients with Parkinson's Disease cognitive dysfunction; and LUMINARY, for patients with Alzheimer's Disease mild cognitive impairment and mild dementia. SAGE-718 was also subject to the DIMENSION study, a double-blind placebo-controlled Phase 2 trial to evaluate the efficacy of once-daily dosage over three months for patients with Huntington's Disease cognitive impairment.

61. These and other clinical trials continued throughout 2021 and into 2022. Ultimately, in May 2022, Sage initiated the rolling submission of an NDA for FDA approval of zuranolone as a treatment for MDD, based, at least in part, on what Defendants publicly characterized as the FDA's purported encouragement and favorable view of the drug and its prospects.

E. Following the Completion of Two Placebo-Controlled Studies Showing Statistical Significance and Efficacy at Six Weeks, the FDA Approves Auvelity—a Fast-Acting MDD Treatment—in August 2022

62. Sage repeatedly described zuranolone as a unique, fast-acting drug for the treatment of MDD. But during the Class Period, another fast-acting treatment for MDD—Auvelity—was well on its way to FDA approval before zuranolone. That drug, developed by Axsome (and mentioned only generally as a competitor in Sage's Forms 10-Q and 10-K), was arguably faster, more effective, and even more durable than zuranolone despite having a different molecular structure and method of action than zuranolone.

63. On March 27, 2019, Auvelity (AXS-05) received Breakthrough Therapy designation for the treatment of MDD from the FDA. The FDA thereafter accepted an NDA for Auvelity, with priority review, in April of 2021. That application was supported by Axsome with two randomized, double-blind, controlled clinical trials in patients with confirmed MDD.

64. Both double-blind studies, GEMINI and ASCEND, had a primary endpoint at six weeks. Both demonstrated effectiveness of the drug from week one through week six with statistical significance. This established Auvelity as a fast-acting treatment for MDD that, unlike zuranolone, also satisfied the FDA's guidance for durability in depression medications. Sage's WATERFALL and CORAL studies, by contrast, had early endpoints at Day 15 and 3, respectively, and showed no statistically significant difference from placebo at Day 42.

65. Yet in Class Period statements about zuranolone, Sage omitted to mention Auvelity and its superior durability in clinical trials. For example, in an earnings call on May 4, 2021, Greene represented, in response to an analyst's question, that zuranolone's study endpoints were sufficient, adding that "[t]here's nothing out there that gets patients better, faster and keeps them better":

> [W]e're very excited and confident in our soon envelope opening for WATERFALL. We're looking forward to the data. And let me just be very clear, the primary endpoint in 15 days having the statistical significance is really what we're looking for this drug. There's nothing out there that gets patients better, faster and keeps them better. Of course, we're looking at all the secondary endpoints and hopeful that they show promise. For day 42, what we're looking for is consistency of effect in the drug arm, not necessarily versus placebo. But again, a p-value on the primary end point is the most important aspect of WATERFALL.

66. In April 2021, however, a few weeks before those statements, the FDA had accepted and granted priority review to Auvelity's NDA—a development that Sage disclosed in its second-quarter 2021 Form 10-Q, in describing potential competition. The FDA later approved Auvelity to treat MDD in August 2022, based primarily on Auvelity's study results of statistical significance and durable efficacy.

67. Despite the FDA's approval of Auvelity—a direct competitor to zuranolone, that also demonstrated rapid onset—Defendants never revised or supplemented their statements to convey to the market that zuranolone was very much at risk of not receiving FDA approval. In fact, according to Greene, Auvelity did not change zuranolone's prospects of success at all.

68. At the September 12, 2022 Morgan Stanley Global Healthcare Conference, an analyst asked Greene if Auvelity's approval changed his view on the commercial potential or positioning of zuranolone. Greene responded:

> It doesn't. And I applaud [Axsome] for getting the drug approved. More options for patients are great. What [Axsome] to me signifies is yet another drug in the wave of getting patients better fast is good. They claim that patients are better in 1 to 2 weeks, which is fantastic, rather than waiting 6 to 8 weeks to get better.

69. As Sage and the other Defendants did throughout the Class Period, Greene failed to mention Auvelity's superior and proven durability at week 6 and neglected to explain that Auvelity's durability would not only significantly affect zuranolone's commercial positioning and commercial prospects, but would also significantly diminish zuranolone's prospects for FDA approval.

70. Armed with information about Auvelity during the Class Period, Defendants surely understood and appreciated, in a way that investors did not, how the FDA might view zuranolone's prospects for approval as a treatment for MDD. Auvelity, by contrast, was not under development for PPD, so an oral treatment like zuranolone had limited competition and correspondingly stronger prospects for FDA approval for that indication. In fact, back then, Zulresso—the only drug Sage had commercialized to that point—was the sole FDA-approved treatment specifically dedicated for PPD.

F. The FDA Denies Approval of Zuranolone to Treat MDD, While Studies of SAGE-718 and SAGE-324 Fail to Demonstrate Efficacy

71. In its May 2, 2022 press release announcing the initiation of the NDA's submission, Sage noted it had submitted the nonclinical module for zuranolone for treating MDD and expected to submit the other components in the second half of 2022. The release also noted that Sage planned to

seek approval for the treatment of PPD in the 2023 first half. The release, however, focused on the potential to treat MDD. Indeed, the title of the release mentioned MDD only, and the text quoted Greene on zuranolone as a treatment for MDD, as follows:

> "There are millions of people living with depression and the initiation of the rolling submission brings us one step closer to our goal of offering zuranolone as a potential new treatment option," said Barry Greene, Chief Executive Officer at Sage. "We believe the results from the LANDSCAPE and NEST programs, in which zuranolone demonstrated rapid and sustained effects and a well-tolerated safety profile in clinical trials, support zuranolone as a potential novel treatment option for MDD, if approved. We look forward to providing an update when the rolling submission or zuranolone in MDD is complete, which we expect to occur in the second half of this year."

72. As 2022 came to a close, Defendants continued to focus on zuranolone's potential application as a treatment for MDD. In a November 22, 2022 press release, for example, Sage said it had scheduled an investor webcast to discuss "the unmet medical need in MDD, review clinical data generated with zuranolone to date and provide more detail on the potential commercialization plans and opportunity in MDD, if zuranolone is approved."

73. On December 6, 2022, Sage issued a press release announcing the completion of the NDA's rolling submission for zuranolone in the treatment of both MDD and PPD. Sage also held its planned webcast. The release and webcast focused on MDD, confirming that commercializing the drug to treat MDD presented a substantially larger and more lucrative market opportunity than PPD.

74. On February 6, 2023, Sage issued a press release announcing that the FDA had accepted the filing, and granted "priority review," of the NDA for zuranolone in treating both MDD and PPD. A month later, on March 8, 2023, Sage announced that the FDA had no plans to convene an Advisory Committee meeting ("AdComm") to discuss the NDA—a development that Defendants positively portrayed, as they had earlier, throughout the Class Period, when discussing whether the FDA would hold an AdComm.

75. On August 4, 2023, however, Sage was forced to announce that the FDA had denied the approval of zuranolone for treating MDD and issued a Complete Response Letter (or "CRL") questioning the efficacy of the drug, and granted approval for PPD only. This development spelled the death knell for zuranolone as a treatment for MDD. Analysts and investors were stunned, and began questioning the implications for Sage's business—and the completeness of Defendants' prior statements about zuranolone.

76. As detailed further below, the fallout from this news was swift and severe. Sage's stock price fell by $19.35 per share—or nearly 54%—almost immediately, and the Company was forced to implement a so-called "strategic reorganization" that called for a 40% reduction in the workforce and refocused priorities.

77. As investors would soon learn, however, zuranolone was not the only pharmaceutical Sage was developing that suffered setbacks. On April 17, 2024, Sage reported topline results from the Phase 2 PRECEDENT study of SAGE-718, disclosing that the drug failed to show statistical significance versus placebo on the primary endpoint in patients with mild cognitive impairment in Parkinson's Disease. In other words, SAGE-718 was no more effective than a placebo over the relevant period studied. As a result, Sage confirmed that it had abandoned plans to develop SAGE-718 for treating Parkinson's Disease. In response to this news, Sage's stock price fell by $3.06 per share, or nearly 20%.

78. Then, on July 24, 2024, Sage reported topline results from the Phase 2 KINETIC 2 study of SAGE-324, revealing that the drug failed to demonstrate statistical significance in the dose-response relationship on the primary endpoint in participants with essential tremor. As with SAGE-718, SAGE-324 was therefore no more effective than a placebo over the relevant period studied. As a result, Sage closed the open label study of SAGE-324 in essential tremor. Again, the fallout was severe, and Sage's stock price fell by $2.70 per share—a decline of nearly 21%.

79. Two months later, on September 26, 2024, Sage announced the discontinuation of its collaboration with Biogen on the development of SAGE-324. As Sage disclosed, Biogen terminated its rights under the collaboration and license agreement as to SAGE-324, and all efforts to develop the drug were discontinued. A month later, on October 17, 2024, Sage announced another "strategic reorganization"—this time, involving the termination of 33% of the total workforce, with 55% of the R&D workforce slated to depart. This reorganization also involved the departure of five senior executives, including Defendant Iguchi.

V. DURING THE CLASS PERIOD, DEFENDANTS ISSUE MATERIALLY FALSE AND MISLEADING REPRESENTATIONS AND OMISSIONS

80. As alleged below, Defendants issued materially false and misleading representations and omissions during the Class Period that concealed adverse information regarding the efficacy and durability of Sage's three leading drug candidates—zuranolone, SAGE-718, and SAGE-324—and the status, nature, and substance of communications with the FDA regarding the Company's NDA for zuranolone for the treatment of MDD. In truth, Defendants consciously or recklessly disregarded this adverse information, which substantially undermined their positive representations, and the risk that their public statements would mislead reasonable investors, during the Class Period.

A. The Class Period Begins with the April 12, 2021 Press Release and Call About SAGE-324 and the KINETIC Study Topline Results

81. The Class Period begins on April 12, 2021. On that date, Sage issued a premarket press release, filed as an exhibit on Form 8-K, announcing topline results from the Phase 2 KINETIC study on the use of SAGE-324 to treat essential tremor. The study evaluated the efficacy, safety, and tolerability of a 60 mg dose of SAGE-324, administered once daily for 28 days to 69 patients with essential tremor with a two-week follow-up period, versus a placebo. The dose could be down-titrated to 45 mg or 30 mg, which occurred in 62% of patients, if 60 mg was not well tolerated; and 38% of patients were discontinued. An objective of the study was to analyze the impact of SAGE-

324 under the Essential Tremor Rating Assessment Scale ("TETRAS"), which gauges, in part, the effect of essential tremor on the activities of daily living (or "ADL").

82. In the press release, Sage reported that the study met its primary endpoint and that SAGE-324 outperformed the placebo "at all time points":

> The study (n=67 full analysis set) achieved its primary endpoint of a statistically significant reduction from baseline compared to placebo in The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale Item 4 upper limb tremor score on Day 29 (P=0.049), which corresponded to a 36% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to a 21% reduction in patients receiving placebo. Activities of daily living (ADL) scores showed a statistically significant correlation with upper limb tremor score at all timepoints. While not powered to fully examine TETRAS ADL, SAGE-324 was numerically superior to placebo at all time points.

83. Sage also reported that administering SAGE-324 during the study appeared to treat more severe tremor:

> In the KINETIC Study, patients (n=47) with a more severe tremor at baseline (at or above the median TETRAS Performance Subscale upper limb tremor Item 4 score of 12) who received SAGE-324, demonstrated a statistically significant reduction (P=0.007) from baseline in TETRAS Performance Subscale Item 4 upper limb tremor score compared to placebo at Day 29, corresponding to a 41% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 compared to an 18% reduction for placebo. Study patients were not taking other medications for ET during the 28-day treatment period.

84. The release quoted a statement from Greene, in which he emphasized the favorable study results and expressed confidence in its continued and future development:

> In the design of the KINETIC Study, we set a high bar and believe we exceeded it. SAGE-324 met the primary endpoint in the trial and demonstrated a safety profile generally consistent with previously reported data. The strong correlation observed in this study between TETRAS performance scale—measuring reduction of upper limb tremor, a disabling symptom experienced by more than 90% of people suffering from essential tremor—and improvement on the ADL score provides suggestive evidence that these findings have the potential to be truly impactful for people with essential tremor . . . .

85. Also on April 12, 2021, after issuing the press release, Sage held a conference call for investors and securities analysts to discuss the topline results of the Phase 2 KINETIC study of

SAGE-324. Eighteen securities analysts attended. Participating on behalf of Sage were Greene, Chief Research Officer Doherty, Chief Medical Officer Kanes, and Investor Contact Jeff Boyle.

86. Setting the stage, Greene first emphasized the demonstrated efficacy of SAGE-324, representing: "as we've been saying for some time, we were looking for a big effect, in the range of 30% to 50% sustained reduction in tremor amplitude from baseline . . . ." Elaborating, he explained that Sage was "looking for the high end of the dose range [to] have the meaningful effect," adding: "This was the high bar, and we believe we exceeded it." He then provided more detail on the study results and their implications:

> First of all, the study achieved its primary endpoint with SAGE-324 demonstrating a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at day 29 in the total study population compared to placebo or the ITT analysis, which corresponds to a 36% reduction from baseline in upper limb tremor amplitude in patients receiving SAGE-324 versus the 21% reduction in patients receiving placebo. And the safety profile was generally consistent with previously reported data from SAGE-324.
>
> Other highlights from the study to point out. Patients with a more severe tremor baseline, those representing the moderate-to-severe patient population, demonstrated a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at day 28, which corresponded to a 41% reduction in upper limb tremor amplitude compared to an 18% reduction for placebo. We believe patients with more severe tumor, that is TETRAS score of greater than 12, represent the majority of ET patients getting diagnosed and seeking treatment today.

87. Acknowledging that the study was not able to fully evaluate the impact of essential tremor on daily living activities, Greene nevertheless represented that SAGE-324 outperformed all relevant factors, contributing to Sage's favorable outlook on developing the drug:

> Importantly, the activities of daily living, or ADL scores, showed a statistically significant correlation with upper limb tremor scores at all time points. Now while not powered to fully examine TETRAS ADL, SAGE-324 was numerically superior to placebo at all time points during the study, demonstrating the clinically meaningful nature of these data and the importance to ET patients.
>
> So hitting statistical significance in the primary endpoint, achieving clinically meaningful reductions in tremor amplitude, seeing the ADL tremor correlation all with an AE profile that was in line with our expectations for the 60-milligram dose is

> [an] encouraging and exciting outcome for this Phase II trial. These data reinforce our belief that the pharmacologic characteristics of SAGE-324 are well suited for development opportunities in essential tremor and possibly other indications. With these new data, we'll work with our collaboration partners at Biogen to optimize next steps for the continued development of SAGE-324 in essential tremor.

88. Later, in response to an analyst question, Greene said that the study yielded optimal results, commenting: "What we are looking for is a 30% to 50% reduction in tremor amplitude over time. We saw that."

89. Echoing those comments, Kanes noted that SAGE-324 "met its primary endpoint, a significant reduction in TETRAS Item 4 upper limb tremor score from baseline at day 29," representing a 36% reduction from baseline versus a 21% reduction for the placebo. He also noted that for more severe tremor, the study confirmed a 41% reduction from baseline at Day 29 compared to 18% for the placebo.

90. Additionally, Kanes noted that "activities of daily living scores showed a statistically significant correlation with upper limb tremor scores at all time points," characterizing the result as "an important consideration" "[f]rom a clinical point of view . . . ." Kanes also said he was "highly encouraged" by the study, noting: "SAGE-324 performed as we anticipated." Later, he expressed further confidence in the findings, telling analysts: "I think the important point here is that now we know that we have a drug which shows the effect, the effects didn't wear out. It didn't wear off or tachyphylaxis"—that is, exhibit a rapidly diminishing response—"over the course . . . ." He assured: "Suffice it to say that these are truly clinically meaningful results."

91. Inquiring about the path toward FDA approval, an analyst sought insight into "how the agency might be weighing the significance of improvements on functional endpoints versus straight tremor reductions . . . ." In response, Greene expressed confidence, stating: "at every time point, activities of daily living were superior for drug versus placebo [and that] gives us tremendous flexibility as we negotiate with the agency." During the call, Greene later said that the "statistically

significant correlation . . . again, gives us tremendous optionality as we work with regulators on what's the most important and on what's most important to patients."

92. In turn, Doherty endorsed these positive portrayals, commenting: "I agree that it's really very, very interesting and very encouraging that we're seeing a good correlation across response to the primary endpoint, the TETRAS scale as well as response to the ADL." Answering a separate question, he also claimed that "the placebo response is more or less in line with what we are hearing from KOLs [key opinion leaders] and others working in the space."

93. Closing the call, Kanes ultimately reiterated the confident tone that all Sage speakers exhibited, representing that the study's results confirmed SAGE-324's benefits in treating essential tremor patients:

> For us, this is, first and foremost, a scientific confirmation that dosing over the course of a month with this mechanism has true differences. Those differences are maintained over time that the mechanism that we've seen repeatedly with multiple drugs, related drugs in this class does holds up into the most, I would say, rigorous scrutiny in a randomized, placebo-controlled trial. And that gives us great confidence to move forward.

94. Many of the April 12, 2021 representations, which instilled confidence in the efficacy of SAGE-324 in treating essential tremor and the drug's performance vis-à-vis placebo, as well as "flexibility" and "optionality" with the FDA stemming from those results, were materially false and misleading. For example:

a. Stating that Sage "set a high bar and believe[d] [to have] exceeded it" in designing the KINETIC study, and promoting the use of the TETRAS scale as a primary endpoint, was materially misleading without disclosure of inherent limitations, known to Sage, in using the TETRAS scale.

b. It was also materially misleading for Defendants to emphasize the "strong correlation . . . between [the] TETRAS performance scale . . . and improvement on the ADL score,"

and to state that "now we know that we have a drug which shows . . . effects" that "didn't wear off or tachyphylaxis," without qualifying those statements with cautionary language about the primary endpoint used. The study "was not powered to fully examine TETRAS-ADL," so even if "SAGE-324 was numerically superior to placebo," that fact, even if true, was of limited probative value and had to be appropriately explained.

c. Likewise, comparing SAGE-324 to the efficacy of competing drugs—by representing that SAGE-324 dosing "maintained over time that the mechanism that we've seen repeatedly with multiple drugs, related drugs in this class does holds up into the most . . . rigorous scrutiny"—again failed to adequately reveal or address limitations inherent to the drug, as well as Sage's already-conceived clinical trials.

95. As investors and analysts later learned, statements like these dramatically overstated the study's results, and the implications for further development (and, ultimately, FDA approval), and the results and structure of the study were insufficient to support overwhelmingly positive statements made without qualification on April 12, 2021.

B. From May Through December 2021, Defendants Continue to Promote Zuranolone, SAGE-324, and SAGE-718, and Discuss the WATERFALL and SHORELINE Studies on Zuranolone

96. On May 4, 2021, Sage issued a press release announcing financial results for the first quarter ended March 31, 2021 (also attached as an exhibit to a Form 8-K filing with the SEC), filed a Form 10-Q with the SEC, and held an earnings conference call with investors and analysts. The Form 10-Q, which Greene and Iguchi signed, contained similar misstatements and omissions as the press release and call. They also signed Certifications under the Sarbanes-Oxley Act of 2002 ("SOX Certifications"), representing that the Form 10-Q is accurate and non-misleading.

97. As the following excerpt reflects, the Form 10-Q addressed Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition: "In April 2021, Axsome

Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which received Breakthrough Therapy designation for MDD in March 2019."

98. The press release quoted Greene, who proclaimed that "the progress we've made so far this year sets us up for near-, medium- and long-term value creation opportunities as we further advance our deep organic pipeline . . . ." As support for that proposition, the release described highlights of reported results in clinical trials of zuranolone, SAGE-324, and SAGE-718.

99. The release discussed topline results reported in March 2021 from the SHORELINE study, designed to evaluate zuranolone's "safety and tolerability . . . in adults for up to one year." According to the release, "[a]fter the initial 2-week zuranolone treatment, more than 70% of patients who received 30 mg and 80% of patients who received 50 mg achieved positive response at Day 15." The 70% of patients who received 30 mg "required at most one additional zuranolone treatment during the 12-month study," consisting of 210 of 489 patients (or 42.9%) who "used only the single initial zuranolone course" and 125 (or 25.6%) who "used a total of two courses . . . ." Of the 199 patients who received 50 mg, "43.2% achieved remission after the initial 2-week treatment period."

100. The release also discussed topline results reported in April 2021 from the KINETIC study, designed to evaluate the "efficacy, safety, and tolerability of SAGE-324 60 mg in patients" with essential tremor aged 18 to 80 years old. As explained, "the daily dose could be down-titrated to 45 mg or 30 mg if 60 mg was not well tolerated," which "occurred in 62% of patients," while treatment was discontinued for 38% of patients. Additionally, "ADL scores showed a statistically significant correlation with upper limb tremor score," and the drug was "numerically superior" to the placebo, at all time points.

101. Lastly, the release discussed results of the Phase 2a open-label PARADIGM study, designed to evaluate the efficacy of SAGE-718 on eight patients, aged 50 to 75 years old with mild

cognitive impairment due to Parkinson's Disease, who received 3 mg daily for two weeks. Noting that "[p]atients showed performance improvements from baseline on multiple tests in the cognitive domain of executive function during the 14 days of treatment," the release reported that "[e]merging signals on several measures also suggested improved performance from baseline on additional cognitive tests in the domains of learning and memory . . . ."

102. Also on May 4, 2021, Sage held an earnings call with 12 analysts. Participating on behalf of Sage were Greene and Iguchi, Chief Research Officer Doherty, Chief Medical Officer Kanes, and Investor Contact Boyle.

103. In prepared remarks, Greene reiterated many of the points expressed in the release regarding Sage's three drugs under development, including their trial results. Thus, for zuranolone, he noted that "[t]he 30-milligram showed that approximately 70% of participants had a positive response to an initial 2-week treatment and required at most 1 additional zuranolone treatment during the 12-month study period," and that "more than 70% of patients who received 30 milligrams and 80% of patients who received 50 milligrams achieved positive response at day 15." For SAGE-324, he noted that Sage sought to establish "a reduction in tremor amplitude of 30% to 50% that was sustained for the full study period" in the KINETIC study—"[i]n other words, no loss of effect or tachyphylaxis"—and that the drug "achieved our objectives and more." And for SAGE-718, "the interim data cut" from the PARADIGM study "showed patients demonstrated improved performance from baseline on multiple tests of executive function over 14 days of treatment."

104. For his part, Kanes emphasized the "great progress across all 3 franchises to date," and recounted the results of the studies addressed in the press release and Greene's comments. For example, as to zuranolone, Kanes noted:

a. "In the 30-milligram cohort at day 15, the mean change from baseline was 15.2 points and 73.5% of patients achieved response. And 40% achieved remission as measured by a HAM-D score of less than or equal to 7."

b. "In the 50-milligram cohort at day 15 of the initial treatment course, the mean HAM-D change from baseline was 16. 80.5% of patients achieved response and 43.2% achieved remission."

105. During the question-and-answer session following the prepared remarks, an analyst referenced "a lot of conversations" he had "with clients about what is acceptable sedation, and what is acceptable somnolence," inquiring: "is there a threshold, a written threshold in the public domain by [the] FDA on what might complicate actual approval either on sedation or somnolence?" In response, Greene assured that data reflected that zuranolone was better than other approved drugs on the market for treating MDD. As he explained, "to date, the profile we've seen is extraordinarily consistent," with "rapid onset of action in 3 to 4 days, patients report they're feeling better," as well as "remarkable efficacy [in] 2 weeks, both 30 and 50 [mg], with most patients requiring only 1 or 2, 2-week doses in the entire year." As Greene further commented: "to be clear, if we hit the primary endpoint, given the different benefit risk of zuranolone, over 35 years' worth of antidepressants, we have a very important medicine in the [Company's] LANDSCAPE [drug development program]."

106. Adding to Greene's comments, Kanes elaborated that "somnolence is something that is often desirable for patients with depression" and that this beneficial side effect led to the "very low dropout rate from our clinical trials." And in indirectly addressing FDA approval just as Greene did, Kanes also claimed that "the numbers that we're reporting are actually comparable, if not better, than many drugs that are used right now to treat depression," explaining: "reports that we have for either somnolence, sedation and so forth, are well within the parameters of drugs that are approved for the treatment of depression, even standard antidepressants."

107. An analyst also sought "information available at the top line" from the WATERFALL study for zuranolone's "durability" of effect beyond 15 days—"maybe longer term, say, 42, things of that nature"—asking "how important . . . based on your doctor feedback" is "longer durability of response for these acute treatment regimes?" In response, Greene claimed "[t]here's nothing out there that gets patients better, faster and keeps them better," but conceded that "we're looking at all the secondary endpoints," noting: "For day 42, what we're looking for is consistency of effect in the drug arm, not necessarily versus placebo."

108. Despite these comments, another analyst emphasized the importance of durability, recounting that "a practice mentioned they couldn't claim MDD treatment if they only treat patients for 15 days" "[s]o they also look at the day 28 data for their MDD drug candidate," and posing two questions: (1) "how important is that [secondary endpoint] day 42 data for [the] zuranolone filing"; and (2) "how did [the] FDA view the open-label SHORELINE study and supporting evidence for the durability of zuranolone?" In response, both Greene and Kanes emphasized zuranolone's primary endpoint of efficacy at Day 15 and "unique" profile.

109. Given these positive comments, an analyst asked about the pathway to FDA approval for zuranolone, as well as "scenario planning" with Biogen, if the results of clinical trials for MDD were adverse: "If WATERFALL and CORAL were to fail, but the Phase III postpartum study were to succeed, would you launch this drug in PPD, and then kind of figure everything else out later, or would you wait?" In response, Greene expressed confidence based, in part, on Sage's discussions with the FDA, referencing three potential pathways to approval:

> [W]e are highly encouraged by the upcoming data readouts. We sat down with the agency and mapped out 3 unique approaches, 3 unique different ways to potentially get approval to an MDD, as you've highlighted, and 1 in PPD. And we believe that 1 of those Phase III needs to be positive for us to have a drug on the market.

> So we're very enthusiastic about all 3 approaches and believe that as you see with many drugs, we need 1 positive Phase III here. And that's an agreement with the agency. Yes, we scenario plan with Biogen at a very high level, but not in any detail.

110. Many of the May 4, 2021 representations were materially misleading because, again, Defendants issued positive statements, or broached particular issues, without providing the factual counterpoint that undermined or otherwise placed in context those representations or the favorable and partial impression they conveyed. For example:

a. The Form 10-Q's disclosure regarding AXS-05, even if technically accurate, failed to reveal additional information about that drug—including the results of studies conducted by then—that was necessary to place in context the implications for zuranolone. Although AXS-05 and zuranolone had different pharmacological mechanisms of action, both were similarly and uniquely positioned as rapid-acting, oral treatments for MDD—and AXS-05 was, in fact, the largest single threat facing zuranolone's prospects for FDA approval. Yet the Form 10-Q described AXS-05 in a general way as a potential competitor, without enough information to gauge AXS-05's prospects for FDA approval. This description deprived investors of detail necessary to appreciate and understand the implications for Sage and zuranolone of AXS-05's potential approval, including, among other things, whether the FDA would consider approving both drugs in succession at or about the same time, whether Sage should design and structure studies for zuranolone similar to those for AXS-05, whether the FDA specifically addressed similarities and differences between the drugs (and provided guidance in that regard), and what approving AXS-05 could mean to zuranolone's potential market share and commercial prospects.

b. Representations regarding zuranolone's efficacy and durability engendered the misleading impression that zuranolone's prospects for FDA approval as a treatment for MDD were better than competing drugs, and that zuranolone had already demonstrated sufficient performance to differentiate zuranolone's prospects from competitors. Thus, for example, Greene emphasized "the

different benefit risk of zuranolone, over 35 years' worth of antidepressants," while Kanes claimed "the numbers that we're reporting are actually comparable, if not better, than many drugs that are used right now to treat depression"—conveying that zuranolone was positioned differently from, and superior to, approved MDD treatments and other competing drugs (presumably including AXS-05).

c. Claiming that "[t]here's nothing out there that gets patients better, faster and keeps them better," and that results at Day 42 simply required "consistency of effect" to demonstrate sufficient durability and effectiveness, were likewise materially misleading. FDA guidance on MDD treatments expressed the importance of lasting and durable effect, and merely showing consistency vis-à-vis placebo at Day 42 would not demonstrate sufficient effect to justify FDA approval. Again, Defendants failed to adequately discuss competing drugs—either approved or under development—that appeared to work just as rapidly and perhaps with a more durable, proven effect.

d. It was also materially misleading to represent that Sage was aligned with the FDA and had "an agreement with the agency," such that zuranolone only "need[ed] 1 positive Phase III here" to achieve FDA approval. In this respect, Defendants failed to discuss how the design and structure of zuranolone's trials, together with FDA guidance, could significantly influence prospects of FDA approval for zuranolone in the treatment of MDD. Instead, Greene and Kanes emphasized zuranolone's claimed unique profile and SHORELINE's efficacy at Day 15, which were insufficient to differentiate zuranolone from existing or prospective MDD treatments to justify approval.

e. Statements that SAGE-324 demonstrated "no loss of effect or tachyphylaxis" and "achieved our objectives and more," and that "the interim data cut" from the PARADIGM study for SAGE-718 showed improved executive function "on multiple tests" over 14 days, also failed to provide proper context for investors to understand the prevailing risks and challenges associated with developing those drugs. These optimistic statements were not tempered or qualified by a description of countervailing facts necessary to fairly assess their credibility and their concrete implications.

111. On June 15, 2021, Sage issued a premarket press release, also attached as an exhibit to a Form 8-K filing with the SEC, announcing topline results from the double-blind, placebo-controlled pivotal Phase 3 WATERFALL study evaluating the efficacy and safety of zuranolone in adults with MDD. The study involved 543 patients with MDD who received 50 mg of zuranolone or placebo nightly for 14 days, with about 90% of patients in each group completing the study. The release stated that the study met its primary endpoint, "showing statistically significant improvement in depressive symptoms compared with placebo at Day 15 as assessed by the 17-item Hamilton Rating Scale for Depression (HAMD-17) total score." The release also indicated that "[p]atients with a response at Day 15 in the zuranolone group retained on average 86.1% of their HAMD-17 improvement at Day 42 (4 weeks after dosing ended)," but said, "[w]hile not statistically significant, a numerical advantage in favor of zuranolone was demonstrated at Day 42."

112. That same day, Sage also held a conference call with 18 analysts and disseminated materials outlining the WATERFALL study results, which Sage's representatives referenced on the call. Participating on behalf of Sage were Greene, Chief Research Officer Doherty, Chief Medical Officer Kanes, and Investor Contact Boyle.

113. In prepared remarks, Greene emphasized that zuranolone met its "primary endpoint," "demonstrating a statistically significant reduction in HAM-D scores at day 15 at the end of the 14-day dosing period," adding: "And perhaps just as importantly, patients who responded to zuranolone at day 15 retained more than 85% of their improvement out to the last time point in the study, day 42. And just to be clear, that's 4 weeks after the last dose of [the] drug." Emphasizing "rapid onset of activity . . . after the second dose, as measured by day 3," Greene referenced earlier results, noting "more than 70% patients receiving a 30-milligram dose of zuranolone needed only 1 or 2, 2-week treatments over the course of a year to maintain wellness . . . ." These representations underscored zuranolone's purported durability in treating MDD.

114. Again, Greene favorably described communications with the FDA, referencing three pathways to potential approval and expressing confidence based on the WATERFALL study: "Now just to remind you, we sat down with the agency and mapped out 3 distinct Phase IIIs, any of which, if positive, was a fileable event. We believe that that's what we have here with WATERFALL." In this respect, Greene cited the WATERFALL study as a significant data point in supporting Sage's forthcoming NDA for zuranolone in treating MDD.

115. In his prepared remarks, Kanes reiterated the results of the WATERFALL study, emphasizing that zuranolone met the primary endpoint and exhibited a lasting effect for 87% of patients even at day 42 (under the MADRS scale). And in concluding his remarks, he differentiated zuranolone from then-available treatments for MDD based on its durability, stating: "As a reminder, current treatment options require chronic dosing, may take up to 4 to 6 weeks to show an effect, if any, and often cause troubling side effects." That claim—that zuranolone was effective long-term—imbued confidence in the drug's prospect for FDA approval, given that competing drugs typically required long-standing and continuous use (which Kanes characterized as "chronic dosing").

116. Based on these remarks, analysts evidently were interested in management's level of confidence in obtaining FDA approval of zuranolone for treating MDD. One analyst asked outright, framing the question thusly:

> I wanted to talk about regulatory, I guess, and I hope you don't mind if it's [a] two-part question. I guess for one, how would you characterize your confidence level that this is truly a positive study from a regulatory perspective, and that a lack of delta, small waning of effect of the drug at day 42 doesn't matter regulatory-wise? And then the second thing on regulatory, maybe you could just comment on what your base case is for how much safety data you'll need in terms of retreatment and long-term follow-up, and whether or not you have that right now or you're likely to need materially.

117. In response, Greene again claimed the Phase 3 trials presented three pathways to approval, stating: "I mentioned on this call, but let me remined you, we set out at the beginning of

the year guiding that after meeting with the FDA, we designed 3 unique Phase IIIs that presented 3 unique opportunities for positive readouts, any of which, if hit, were a fileable outcome." He then cited the WATERFALL study's "very statistically significant p-value at day 15," noting, with those results "we believe that we have a fileable data." Greene reiterated this sentiment in response to a later question, representing that the WATERFALL data were sufficient for approval even if results from the ongoing CORAL study were negative:

> [W]e have 3 unique Phase IIIs. Any one of which, if positive, is fileable. So positive CORAL would be great, but it's not needed for approval. We believe that what we see in WATERFALL is what we need for a drug to be approved.

118. In a separate response, Kanes highlighted the drug's durability, which he called the "maintenance of efficacy":

> [W]ith regard to regulatory, the way that we're thinking about maintenance of efficacy, we've had this question before with ZULRESSO, what's important here is stability. And we certainly have demonstrated that across the entire program with more than 85% of patients maintaining benefit. So overall, we're looking forward to having those discussions with the FDA. But this is clearly fileable, and as Barry said, we're looking to think about the most efficient way to do that.

119. An analyst also queried what would be important to physicians in "decid[ing] whether to prescribe the drug," asking if they should "merely look at the delta versus placebo at day 15 and day 42[.]" Greene responded "[o]bviously, we're thrilled with these data," adding that "physicians will reach for zuranolone either alone or concomitant with another antidepressant, which doesn't necessarily help get them out of the depressive symptoms but can help them, once better, stay well as we've seen with zuranolone." In turn, Kanes focused on zuranolone's purported rapid response and extended efficacy, extolling the drug's reliability:

> [A]t the end of the day, we know that in clinical trials, people talk about placebo and delta from placebo. For clinical treatment, it's how quickly do patients get better, how much better do they do and what happens after they stop therapy. And what's unique about this and absolutely different from everything that's out there is the ability to treat patients quickly, a 2-week course of therapy, and then know that if

> they need additional retreatment as we've seen in SHORELINE, they'll have reliable response again. That's something very, very different.

120. When an analyst asked for more detail on zuranolone's effectiveness—inquiring, "[i]n the context of the delta that you saw on HAM-D," to "put the placebo response in respect of what it's been seen prior"—Greene said "the reduction in HAM-D scores in the WATERFALL are clinically meaningful," adding: "And just to emphasize, what's important here again is that patients got better rapidly and stayed better longer with maintenance of effect out to day 42, and that's what matters most to patients."

121. Also responding, Kanes minimized the placebo's importance, representing that "[t]he consistency that we've seen in terms of the overall benefit for patients on zuranolone has been rock solid since our first study . . . ." He then attributed the difference between zuranolone and placebo to natural and unavoidable "variability," necessitated by complications related to assessing depression:

> And so the delta from placebo, that's driven entirely by the variability that we see in placebo. And that's a constant challenge within depression trials. It's one of the reasons why we emphasize what it is that the drug does as opposed to trying to war game out what that delta from placebo is.
>
> So at the end of the day, as we said, the large drops in terms of symptoms as well as the maintenance of efficacy is what really matters to patients. And from a physician and from patient perspective, those are the things that are absolutely critical for when they would choose to use this and for which patients.

122. In turn, Doherty agreed that "placebo response does vary," indicating that zuranolone showed "rapid response as early as day 3" that "maintained out through time," while "the placebo response" occurred "through day 15." Yet like Greene and Kanes, he did not meaningfully explain whether the placebo response undermined zuranolone's trial results, instead suggesting the opposite: that natural variability in placebo response did nothing to detract from zuranolone's rapid response and continued efficacy for the duration of the periods tested. Later during the call, when an analyst

asked about "the maintained response rate for placebo," Kanes relayed a similar message and shifted focus to the primary endpoint of the study:

> So the placebo was maintained. I mean we see placebo across all of our trials. And that's why our—obviously, we didn't separate from placebo at day 42. A little less relevant because if you look in the real world, the placebo responses aren't what and what no treatment really refers to. And that's one of the challenges in this field, but really, the important part here is day 15 in the primary endpoint.

123. That analysts continued to place significance in zuranolone's trial results was evident when another conference call participant asked whether Sage "calculated remission and response," noting "it sounds like it would be important to doctors both at day 14 and day 42." Discussing "the secondary endpoints, relapse and remission rates," Doherty said that "response and remission rates are really consistent with the pooled response and remission rates across the placebo-controlled Landscape and Nest studies, including both MDD and PPD." And again, he noted: "the key point is that patients are getting better fast, and they're maintaining that improvement out through the study."

124. Durability also remained important to analysts, with one asking: "When you think about durability and maintenance of effect of 86% at day 42, how far would that effect have to fall before more physicians or patients would think about restarting therapies?" Kanes responded that SHORELINE "actually looks to answer that question," noting "about 70% of patients require no more than 1 additional treatment in a year using standard diagnostic criteria," "[s]o that's really better to understand what the rate of retreatment might be than rather—rather than at 30 days." To place that response in context, he added:

> So we looked for where our triggers of true MDD, where patients actually have recurrence of symptoms. And as I said, 50% of patients didn't require any additional therapy over the course of the year, and 70% required—excuse me, 70—the additional 20% only required 1 additional treatment. So a really durable response and an important option for patients if approved.

125. Greene echoed that sentiment, reemphasizing zuranolone's durability and dubbing the length of response "almost a reverse placebo effect":

> [J]ust to highlight, what's remarkable there, again, 70% of patients, that was a 30-milligram group, only required 1 or 2, 2-week courses. So that's 4 weeks of drug out of 52 weeks, being drug-free for the rest of the time. That's important to patients. And what's really critical and often missed here, not by physicians per se, is that they know they're off drug, and yet they're still maintaining that benefit. It's almost a reverse placebo effect, if you will.

126. Later, Greene cited zuranolone's "durable effects out to day 42," while Kanes said the "data continue to support what we've known about this drug for quite some time: rapid, very large effects and durable effects that we can use to treat patients episodically." Separately, Kanes claimed "the metric of just trying to understand difference from placebo, it could be misleading," explaining: "What you need to look at is how large an effect was there for patients, would they notice it." He added: "[T]hose large effects are what's different. Placebo will do what placebo does, but we're seeing some very dramatic and very different effects over a very short period of time. And it just bears repeating that we're talking about these effects being durable after only 2 weeks of therapy."

127. Many of the June 15, 2021 representations, which were lengthy and voluminous, were materially misleading. As shown above, these representations often repeated or reiterated the same points, conveying and reinforcing the reliability and credibility of the impression that zuranolone was already well positioned for FDA approval and that further clinical studies would simply bolster that conclusion. For example:

a. By emphasizing that WATERFALL met its primary endpoint of "showing statistically significant improvement in depressive symptoms compared with placebo at Day 15," and "a numerical advantage in favor of zuranolone" at Day 42, Defendants misleadingly conveyed that demonstrating short-term improvement in depressive symptoms was arguably more important than proving a correlation between zuranolone and long-term, durable efficacy. By its very nature, "numerical advantage" merely implies, in context, that a drug is more effective than placebo, without supplying any reason for the difference in performance or establishing a statistically significant link

between the drug and the effect. That zuranolone had a "numerical advantage" at Day 42 proved little about its durability, despite the impression that Defendants conveyed—when they said patients "retained more than 85% of their improvement," and experienced lasting effect, out to Day 42.

b. In fact, Greene's statement that "what's important here again is that patients got better rapidly and stayed better longer with maintenance of effect out to day 42" lacked factual support precisely because there was a statistically significant difference from placebo at Day 42. Thus, Defendants could not reasonably link the so-called "maintenance effect" to zuranolone Greene emphasized, when both zuranolone and the placebo performed similarly at Day 42. With durability lacking for zuranolone, Greene's statement that long-term "maintenance" of effect resulted from using zuranolone was, accordingly, materially false and misleading.

c. Comparing zuranolone to Zulresso and representing that "what's important here is stability" (as Kanes did), and claiming "patients got better rapidly and stayed better longer with maintenance of effect out to day 42" (as Greene did), affirmatively represented that zuranolone satisfied the FDA's criteria for approval and differentiated the drug from other treatments, perhaps even including Auvelity/AXS-05 (albeit not referenced directly). Along these lines, Greene claimed that zuranolone showed "durable effects out to day 42," Doherty said "the key point is that patients are getting better fast, and they're maintaining that improvement out through the study," and Kanes represented that "it just bears repeating that we're talking about these effects being durable after only 2 weeks of therapy"—all of which conveyed that zuranolone was sufficiently durable for approval, despite lacking statistical significance out to Day 42 in the WATERFALL or other MDD study. To this end, Greene—who declared "we're thrilled with these data"—stated, in no uncertain terms: "We believe that what we see in WATERFALL is what we need for a drug to be approved."

d. Equally misleading, if not more so, were repeated representations about the meaning, interpretation, significance, and implications of the WATERFALL study results regarding

zuranolone's long-term efficacy versus placebo. By representing that "the metric of just trying to understand difference from placebo" could itself somehow be misleading, Defendants ironically and misleadingly downplayed the importance of the lack of statistical connection between zuranolone and efficacy at Day 42. Kanes claimed it is futile to "war game out what that delta from placebo is" and "that's a constant challenge within depression trials," advocating instead to focus on "what it is that the drug does"—while stating, dismissively, "[p]lacebo will do what placebo does." In fact, Greene framed zuranolone as having "almost a reverse placebo effect," where patients take "4 weeks of drug out of 52 weeks," and then when "off drug," "they're still maintaining that benefit . . . ." These and similar representations had the intended effect of downplaying and otherwise minimizing zuranolone's inability to demonstrate the statistically significant long-term effect required for FDA approval in the crowded field of MDD treatments.

128. This news revealed that for MDD patients, zuranolone demonstrated only a purported "numerical advantage"—not a statistically significant response—in the WATERFALL study at Day 42, which concerned the market. In response to this news, Sage's stock price declined substantially, closing at $58.80 per share on June 15, 2021—a decline of $14.06 per share, or 19.3%, from $72.86 on June 14, 2021—on volume of nearly 8.6 million shares traded, almost eight times more than the volume on June 14. The stock price also declined on elevated trading volume the next day, June 16, 2021, as the market continued to digest this information. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
June 14, 2021	$79.25	$79.32	$72.06	$72.86	1,083,800
June 15, 2021	$65.00	$67.48	$58.26	$58.80	8,591,600
June 16, 2021	$56.92	$58.68	$53.80	$54.88	4,535,300

129. The stock price remained artificially inflated, however, as Defendants continued to conceal, obscure, and misrepresent zuranolone's efficacy and durability, as well as the reasonable prospect of FDA approval of zuranolone for the treatment of MDD.

130. On July 13, 2021, Greene and Kanes presented at the Cowen Psychedelics & Novel Mechanisms in Neuropsychiatry Summit. Almost immediately, Kanes emphasized the durability of zuranolone, as the following passage reflects:

> And in study after study, we've been able to demonstrate that we're improving those core symptoms. And we're in a durable way, long after the patients have stopped taking medication. And we saw that in the WATERFALL study, perhaps most dramatically in our SHORELINE trial, which is where patients were treated for 2 weeks at a time, and we've seen that greater than 70% of patients needed no more than 2 treatments or 2 14-day course of treatments in a year. So really long, durable effects on depression, which we think is transformative for patients.

131. Kanes and Greene also continued to downplay the importance of the placebo effect exhibited in the WATERFALL study. Indeed, when the host asked "how should we be thinking . . . of the magnitude of the placebo effect that we saw" in the WATERFALL study, Greene claimed that "the totality of the data" showed that zuranolone worked rapidly and said a patient "might only need 2 or 4 weeks of therapy in the course of the year." And he echoed Kanes's June 15, 2021 statements, claiming "our industry has been trying to figure out placebo effect on depression studies for a couple of decades, 35 to 50 years," adding that the Company had all the information it needed for approval:

> [T]hat's a big challenge. What's important—and obviously, when you conduct the clinical studies, you want to minimize placebo so that you tease out the drug effect. We've done that. As early as January, Steve and I were saying to everybody, "All we're looking for is a statistically significant result at day 15 and no surprise on adverse event." We've got that along with the other positive study, the totality data, we believe we have an approvable package, and we stand on that today.

132. As the call proceeded, Greene continued to minimize the importance of the placebo effect, at one point saying: "Importantly, we emphasize again, even as robust [as] the placebo effect was, the drug effect was clear and in the range and held out to day 42." Even when asked "about the sort of decline of effect at day 42" and whether that "means there is no discernible effect at that time point," Kanes shifted the focus away from the placebo effect and focused on the purported "benefit" of zuranolone based on what he called the "raw numbers":

> What we're referring to here is something that's really important conceptually, which is rather than thinking about delta from placebo at day 42, we look to see whether patients maintain their benefit. And what we said is that when you look at the overall change from baseline at the end of treatment, you carry that out through day 42 and you look at whether or not those numbers are the same.
>
> So it's 2 things we learned. One, those numbers are not statistically different. So we know that patients aren't having statistically significant changes in their overall change from baseline. The other is that if you just use the raw numbers, it's 87% of the benefit that they had seen at day 15.

133. The July 13, 2021 statements continued to convey materially misleading information about zuranolone and the prospects for FDA approval, ensuring that Sage's stock price remained artificially inflated. For example:

a. Kanes described zuranolone as "transformative," claiming that "study after study, we've been able to demonstrate that we're improving those core [depressive] symptoms" "in a durable way, long after the patients have stopped taking [the] medication . . . ." These statements reinforced the conclusion that clinical studies had repeatedly confirmed zuranolone's long-lasting and durable efficacy after rapid onset, when, in fact, zuranolone's durability was unproven and the drug had never exhibited statistical significance out to Day 42 in any MDD-related study.

b. Greene and Kanes continued to minimize the importance and implications of zuranolone's long-term performance versus placebo, with Greene specifically "emphasiz[ing] again, even as robust [as] the placebo effect was, [that] the drug effect was clear and in the range and held out to day 42," and Kanes reiterating from June 15, 2021 that "rather than thinking about delta from placebo at day 42, we look to see whether patients maintain their benefit[.]" Greene also referenced prior statements in pointing out "[a]ll we're looking for is a statistically significant result at day 15," adding: "We've got that along with the other positive study, the totality data, we believe we have an approvable package, and we stand on that today." These representations continued to lead investors

to believe that zuranolone had already demonstrated the type of efficacy required for FDA approval and that the failure to differentiate efficacy from placebo after two weeks was inconsequential.

134. On August 3, 2021, Sage issued a press release announcing financial results for the second quarter ended June 30, 2021 (also attached as an exhibit to a Form 8-K filing with the SEC), filed a Form 10-Q with the SEC, and held an earnings conference call with investors and analysts. The Form 10-Q, which Greene and Iguchi signed, contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

135. As the following excerpt reflects, the Form 10-Q continued to address Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition: "In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which received Breakthrough Therapy designation for MDD in March 2019."

136. The press release highlighted quarterly developments, repeating information that Sage previously disclosed, such as topline results of the WATERFALL study. Thus, Sage noted that the study "met its primary endpoint demonstrating statistically significant and clinically meaningful improvement in depressive symptoms compared with placebo at Day 15" on the HAMD-17 scale, and that patients who responded to the drug on Day 15 "retained on average 86% of their HAMD-17 improvement at Day 42 (4 weeks after dosing ended)."

137. In the release, however, Sage revealed it was "formally terminating the REDWOOD and RAINFOREST Studies, which were suspended in the first quarter of 2020"—a decision Sage attributed to discussions with the FDA. To explain this decision, Sage again invoked its discussions with the FDA, stating: "After discussions with the FDA, Sage does not believe that these studies will be required for a potential NDA submission."

138. The release also disclosed that: (1) in the KINETIC study, "SAGE-324 demonstrated a statistically significant reduction from baseline in the TETRAS Item 4 upper limb tremor score at Day 29 . . . [as] compared to placebo" and "a statistically significant correlation between TETRAS tremor score and [ADL]"; and (2) the PARADIGM and LUMINARY studies were then underway for SAGE-718, with additional testing slated for late 2021.

139. That same day, Sage held a conference call with 11 analysts and issued presentation materials. Participating on behalf of Sage were Greene and Iguchi, Chief Medical Officer Kanes, and Investor Contact Boyle. In his prepared remarks, Greene first described topline data from the WATERFALL study on zuranolone, reiterating that Sage "saw a clear maintenance of effect through day 42, 4 weeks after treatment was stopped." Referencing planned communications with the FDA, he said "we believe we have the efficacy data in hand to file the first NDA for zuranolone . . . ." He also recounted previously reported results of clinical trials in SAGE-324 and SAGE-718.

140. Additionally, Greene addressed Sage's reasons for terminating the REDWOOD and RAINFOREST studies, claiming those studies were unnecessary to secure FDA approval in view of the SHORELINE study:

> As you may recall, REDWOOD was designed to study fixed schedule intermediary dosing of zuranolone throughout the course of the year. We believe data from the SHORELINE Study address this question. [Because] RAINFOREST was designed to investigate the efficacy and safety of zuranolone in comorbid MDD and insomnia, while zuranolone has consistently improved sleep across clinical studies as measured by sleep component of the HAM-D scale, we do not believe RAINFOREST is required for initial filing.

141. In his own prepared remarks, Kanes also recounted previously reported results of clinical trials in zuranolone, SAGE-324, and SAGE-718, but spent the bulk of his initial comments on zuranolone. Citing the WATERFALL study, he reiterated that "patients who responded to zuranolone after 2 weeks of treatment retained on average more than 85% of their improvement through the end of the trial"—"a full 30 days after the last does of mediation with the majority of

these patients maintaining most, if not all, of the improvement." Supporting Greene's comments, Kanes also claimed that "the data we've generated to date" and "ongoing pharmacology studies" were sufficient for "the regulatory NDA filing pathway."

142. Noting that the CORAL and SHORELINE studies were ongoing, Kanes nevertheless represented that "[t]he positive results from the, WATERFALL Study, we believe, have sufficient efficacy data to support our first FDA filing for zuranolone." Yet he expressed unbridled confidence that CORAL would yield favorable results, commenting: "of course, we expect to see [a] consistent efficacy profile supporting the differentiated benefit/risk of zuranolone in this trial, including rapid onset of effect."

143. During the question-and-answer session, analysts focused on the regulatory strategy for zuranolone, with one asking if CORAL was necessary for a successful application for MDD and whether "the FDA had indicated that SHORELINE would provide sufficient retreatment data for the [NDA] filing" in view of the "decision to terminate REDWOOD and RAINFOREST . . . ." Greene responded that Sage is "in an ongoing dialogue" with the FDA, claiming that the Company is "able to confirm REDWOOD and RAINFOREST would not be required for this filing" and that data from SHORELINE are sufficient "to provide the retreatment evidence."

144. Later, Greene claimed that zuranolone would "get an indication for both MDD and PPD, which is what we expect . . . ." Characterizing zuranolone as a "2-week therapy" for treating MDD, he indicated that "most of the improvement happens within the first week," with incremental improvements "[b]y the end of 2 weeks" and "somewhere between 40% and 50% remission . . . ." As a result, Greene claimed, "the time limited aspect of this is what got the FDA's attention [and] is why we have a breakthrough [designation] in the first place."

145. Many of the August 3, 2021 representations were materially misleading when made. These representations, on the whole, continued to reference non-public interactions with the FDA to

outwardly convey confidence in Sage's plans for obtaining approval of zuranolone—and instill and induce investor confidence, in the process—while maintaining stock price inflation. For example:

a. The Form 10-Q's disclosure on AXS-05 continued to reveal only partial and limited information about that drug, despite that it was further along in the process for FDA approval than zuranolone. Indeed, this disclosure was identical to the earlier disclosure in the Form 10-Q on May 4, 2021, three months before. But AXS-05 remained the largest single threat to zuranolone's prospects for FDA approval.

b. Multiple representations referenced non-public communications with the FDA to explain Sage's termination of zuranolone's REDWOOD and RAINFOREST studies, which Sage, Greene, and Kanes claimed were unnecessary to file an NDA seeking approval. In fact, Greene said that Sage "is in an ongoing dialogue" with the FDA, which confirmed those studies were not needed. Indeed, Kanes said "[t]he positive results from the, WATERFALL Study, we believe, have sufficient efficacy data to support our first FDA filing for zuranolone"—which Greene confirmed, when he said "we believe we have the efficacy data in hand to file the first NDA for zuranolone . . . ." These statements expressed unqualified confidence that Sage had all of the efficacy-related data necessary to obtain FDA approval for zuranolone in treating MDD. In truth, Defendants understood that proof of long-term, statistically significant efficacy—like Auvelity had demonstrated—was necessary, yet they concealed that fact from investors.

c. Also materially misleading were Greene's statements that zuranolone could "get an indication for both MDD and PPD, which is what we expect," and "the time limited aspect of this"—referring to zuranolone's initial two-week treatment regimen and rapid onset—"is what got the FDA's attention [and] is why we have a breakthrough [designation] in the first place." Framing what was important to the FDA in this way was misleading, because Greene unreasonably elevated the importance of zuranolone's dosing and onset above Sage's ability to prove its lasting efficacy in

clinical trials. The repeated references to Sage's dialogue with the FDA only lent credence to these types of representations, which imbued investors with a false sense of confidence in the roadmap to FDA approval for zuranolone in MDD that Defendants promoted publicly.

146. On August 11, 2021, Greene presented at the Canaccord Genuity Growth Conference, where the host raised the efficacy of zuranolone at Day 42. The question implied that zuranolone exhibited similar effectiveness to placebo, which Greene called "a big misinterpretation" of "the WATERFALL study for day 42." As previously, Greene minimized the importance of the placebo results, claiming that "most of those patients at day 42 were as well or better than they were at day 15," commenting: "clearly, we have an overperforming placebo that throws off the graph." He also repeated prior statements, noting that "what's really interesting about SHORELINE, and it's unique in the study of depression, is it's almost a reverse placebo effect."

147. Underscoring confidence in securing FDA approval, Greene said Sage "sat down with the agency . . . after the MOUNTAIN study, which just barely missed stat sig"—that is, statistical significance—"and all appreciated that we have a drug, zuranolone, that works." Analogizing that experience to the popular antidepressant Prozac, which purportedly failed seven out of eleven Phase 3 trials before obtaining FDA approval, Greene then claimed that the Company met with the FDA to develop a clear pathway to approval:

> So we sat down with the agency, we said, what's the right path to approval? We designed 2 studies for MDD: WATERFALL, which we read out positively; CORAL, which is coming up; and then another PPD study, SKYLARK. Any one of which, if positive, provided the efficacy data set to file on.

148. Claiming "[w]e have the efficacy data we need for filing" and that Sage "confirmed" with the FDA "that statistical significance at day 15 is not necessarily a requirement for [the NDA's] filing," Greene explained that Sage developed a filing package that proved zuranolone's efficacy in treating MDD was sufficient for FDA approval:

> So what we believe we have today is we have the efficacy data for a fileable package now that we have that next complete positive Phase III with WATERFALL. So we have the efficacy package. We've said -- we said at the beginning of the year, and we sort of have tried to repeat this, we chose to rerun the pharmacology studies at 50 milligrams. We had the 30-milligram complete, but we're rerunning them at 50. Those studies will be done kind of at the end of the year."
>
> Why? We didn't want to leave any room for interpretation about any boxes that didn't get checked as we filed for the NDA. This is a large indication, millions of patients. So we want to make sure that we provide the highest quality data package. We expect no surprises with the repeat pharmacology studies. And then because it's in zuranolone's best interest because of the clean safety profile, our intention is to take a blinded look at all safety on ongoing clinical studies as part of the package.
>
> Now we expect CORAL to be complete as we've guided. So with a complete CORAL, both efficacy and safety, that will get integrated into the package. But we've said historically, and we confirmed this with the agency, that unless we see some strange pattern, it doesn't work on day 3, 8, 12 or 15, that statistical significance at day 15 is not necessarily a requirement for filing. We have the efficacy data we need for filing. This is yet another study.

149. Given those comments and "unpredictability with the FDA recently," the host pressed Greene on Sage's communications with the FDA, asking "when was your last discussion with the agency to ensure that you are completely on board with the regulatory requirements?" The host then asked if it was "fair" to assume that "the last discussion [with the FDA] was the one that resulted in not requiring REDWOOD and RAINFOREST[.]" Greene claimed that because zuranolone received "breakthrough status" from the FDA, "ongoing discussions" guide the process:

> [G]iven the breakthrough status that we have with zuranolone and given the way breakthrough works, there's ongoing discussions with the agency. Some of those discussions are more strategic, which leads to decisions to not run certain trials, like you mentioned.
>
> Some of the more tactical, in terms of dates and time and sort of administratively, do we do a rolling submission? Do we do a full submission? The kind of formal meeting where we do the official Type B NDA meeting, that's coming up in kind of weeks, not months. And once we have that formal meeting with sort of everybody present that locks in the data sets, all the administrative steps, as we've said before, we'll come out in a Reg FD format with Biogen and clarify what we believe we and the agency have agreed for the path forward. I do expect it to be as we've already articulated.

150. Greene even invoked comments about zuranolone he had made at other conferences, noting that Sage "likened it to a "Z-Pak," explaining that when someone is "heading to a depressive episode," "[t]hat's when you treat and get them better with zuranolone." The clear takeaway from these comments was that Defendants drew confidence from ongoing interactions with the FDA as a result of zuranolone's "breakthrough designation," and that the Company adapted its clinical trials—terminating some and pursuing others—with the FDA's "strategic" guidance. According to Greene, the revolutionary nature of the drug—allowing episodic treatment with rapid and long-lasting effect, as opposed to continuous and lengthy treatment with delayed effect—magnified the drug's prospect for FDA approval.

151. Many of the statements on August 11, 2021 were materially misleading for the same reasons as Defendants' previous statements. The actionable August 11, 2021 statements involved three main issues: communications with the FDA; the implications of performance versus placebo; and zuranolone's short-term efficacy. For example:

a. Greene again attempted to induce confidence in Sage's roadmap for approval for zuranolone in treating MDD, representing that Sage "sat down with the agency . . . after the MOUNTAIN study, which just barely missed stat sig [statistical significance] and all appreciated that we have a drug, zuranolone, that works." In the MOUNTAIN study, zuranolone failed to meet the primary endpoint of a statistically significant reduction from baseline to placebo in the HAM-D total score at Day 15. Given that Sage reported those results in December 2019, however, Greene's statement misleadingly conveyed that the FDA had communicated that zuranolone was an effective treatment for MDD years ago despite the results—which, of course, also misleadingly conveyed that the FDA held a long-standing, favorable view of zuranolone that would only simplify and expedite the FDA review and approval process now. To this end, Greene also claimed that "there's ongoing discussions with the agency," noting some "are more strategic, which leads to decisions to not run

certain trials"—evidently implicating Sage's RAINFOREST and REDWOOD study terminations, which Greene again claimed resulted from discussions with the FDA about the studies necessary for MDD approval.

b. Hinging off of the representation that the MOUNTAIN study did not hamper zuranolone's prospect for FDA approval, Greene also represented that "we've said historically, and we confirmed this with the agency, that unless we see some strange pattern, it doesn't work on day 3, 8, 12 or 15, that statistical significance at day 15 is not necessarily a requirement for filing." He then again confirmed that Sage "ha[s] the efficacy data we need for filing" zuranolone's NDA for MDD based on the WATERFALL study, claiming: "we believe we have today is we have the efficacy data for a fileable package now that we have that next complete positive Phase III with WATERFALL." Again, Greene's references to non-public FDA communications suggested that the FDA confirmed that WATERFALL's efficacy data was sufficient for approval.

c. Yet Greene explained away the placebo effect, claiming "an overperforming placebo . . . throws off the graph" and again invoking the "reverse placebo" characterization from June 15, 2021. Specifically, he claimed that "what's really interesting about SHORELINE, and it's unique in the study of depression, is it's almost a reverse placebo effect." At the same time, Greene "likened" zuranolone to a "Z-Pak," explaining that zuranolone could be administered periodically to provide fast relief when a person is "heading to a depressive episode[.]" These statements continued to misleadingly represent that zuranolone's short-term efficacy was sufficient for an NDA filing in MDD, and that data on placebo performance was unhelpful because it skewed and undermined an otherwise accurate portrayal of zuranolone's efficacy.

152. In September and October 2021, Greene continued to promote zuranolone as a fast-acting and lasting treatment for MDD, repeating many of the misleading statements that Defendants made previously, on other occasions. For example:

a. At the Morgan Stanley Global Healthcare Conference, held on September 10, 2021, Greene represented that zuranolone "works rapidly" and said "we see durable responses based upon the WATERFALL study and the SHORELINE study," adding: "Nobody's imagined a world where you literally could treat someone with 2 weeks of evening therapy and get them better, faster and keep them better." He also again referenced discussions with the FDA: "What the team did with the agencies [is] designed 3 different Phase IIIs, any one of which [if] hit based upon the rest of the data led to a fileable package, 2 in MDD and 1 in PPD." Adding specificity, he revealed that Sage "talked to the agency about 4 different times" in developing these three approval paths—"3 different studies, 3 unique designs, any one of which [if] hit gave us a viable package."

b. On October 4, 2021, Sage issued a press release and held a conference call, which ten analysts attended, reviewing data regarding zuranolone. Participating in the call on behalf of Sage were Greene, Doherty, Kanes, and Investor Relations Officer Helen Rubinstein, as well as Dr. Anita Clayton ("Clayton"), an investigator in the clinical development program who reviewed presentation materials. Clayton, speaking on behalf of Sage, claimed that "clinical trials" showed that zuranolone's "short-course, 14-day treatment, has led to a rapid, robust and sustained improvement in depressive symptoms and has shown a differentiated and well-tolerated safety profile . . . ." Even so, an analyst asked "how sustained both the response and remission rates were at day 42" versus Day 15 and the "placebo rates of both of these measures[.]" Greene responded that "consistency across all studies" and the "response/remission when coupled with all the other data" "gives us tremendous confidence in how zuranolone is performing," while Kanes highlighted "both response and remission for longer duration"—claiming "[o]nce patients get better, they remain well"—and Clayton essentially dodged the placebo question, citing zuranolone's rapid effect. When asked to express the importance of "remission at day 15 and 42" from a regulatory standpoint, Kanes claimed the predominant factor for the FDA is "does the drug work?"

153. The September 10, 2021 statements that Sage spoke with the FDA "about 4 different times," and confirmed that zuranolone had three pathways to approval, were materially misleading without disclosure that the FDA, in fact, required evidence of statistical significance of longer-term efficacy versus placebo—which the Company had yet to achieve in any study designed for MDD. Again, Greene claimed "we see durable responses" based on the WATERFALL and SHORELINE studies, but those studies failed to establish long-term efficacy. Yet on October 4, 2021, Greene cited "consistency across all studies" in claiming "response/remission," with "all the other data," "gives us tremendous confidence in how zuranolone is performing"—another materially misleading representation, intended to promote confidence in zuranolone's chances for FDA approval.

154. On October 19, 2021, Sage issued a press release, attached as an exhibit to Form 8-K, announcing plans to file the NDA for zuranolone. According to the release, Sage planned to file an initial submission package for MDD and a filing for PPD thereafter. Citing talks with the FDA, the byline of the release read: "Following the pre-NDA meeting, the companies confirmed the current efficacy and safety databases are expected to be adequate for filing with confirmed pathways for MDD and PPD[.]" Addressing that meeting, the release quoted Greene, who said: "In the pre-NDA meeting, the FDA's response on the regulatory pathway for zuranolone continued to be consistent with previous discussions." As if to instill further confidence in approval, the release closed with statements that Sage and Biogen "plan to commence marketing for the approved indications as soon as possible pending the FDA's approval" and that "[t]he review cycles may allow commercialization of both indications simultaneously, if approved."

155. The October 19, 2021 reference to discussions with the FDA was simply the latest in a long line of references to those non-public discussions, which were independently unverifiable for investors and analysts. Yet these representations had the intended effect of assuaging any potential concerns about zuranolone's prospects for FDA approval as a treatment for either MDD or PPD,

given that Sage purportedly "confirmed the current efficacy and safety databases are expected to be adequate for filing with confirmed pathways for MDD and PPD[.]"

156. On November 2, 2021, Sage issued a press release announcing financial results for the third quarter ended September 30, 2021 (also attached to Form 8-K), filed a Form 10-Q with the SEC, and held an earnings conference call with investors and analysts. The Form 10-Q, which Greene and Iguchi signed, contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

157. As the following excerpt reflects, the Form 10-Q continued to address Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition: "In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which received Breakthrough Therapy designation for MDD in March 2019."

158. The press release first quoted Defendant Green, who attempted to instill confidence in the approval process by referencing what he called "a successful pre-NDA meeting with the FDA for zuranolone." Citing "clinical development to date" on zuranolone that allegedly showed "sustained reductions in depressive symptoms," he stated: "We're excited to have reached alignment with the Agency and to have what we believe is a clear, efficient path forward for zuranolone."

159. The release also separately referenced communications with the FDA in the context of a forthcoming NDA for MDD, representing: "The decision to submit the application follows discussions with the FDA, including a pre-NDA meeting held this fall." Elaborating on the meeting, the release explained that interactions with the FDA "reinforced Sage's belief" that its clinical trial data "will be sufficient for Sage to file in MDD":

> The meeting reinforced Sage's belief that data from the MDD-201, ROBIN, and WATERFALL Studies and the Shionogi Phase 2 study along with supportive data from the MOUNTAIN Study will be sufficient for Sage to file in MDD. The planned initial NDA will focus on MDD and will also include data from the ongoing pharmacology and clinical studies (CORAL and SHORELINE Studies).

160. The release also reported that Sage announced that day "that the primary endpoint for the CORAL Study (HAMD-17 change from baseline) will be measured at Day 3" (instead of Day 15), noting CORAL was "an adjudicative use study in MDD designed to demonstrate the benefit of zuranolone when co-initiated with a new antidepressant therapy . . . ." The Company indicated that "additional data" from the study "may be important to inform real world use in MDD if zuranolone is approved."

161. That same day, Sage held a conference call with 12 analysts and issued presentation materials. Participating on behalf of Sage were Greene, Iguchi, Kanes, Doherty, and Rubinstein. In his prepared remarks, Greene characterized the pre-NDA meeting with the FDA as a milestone that induced confidence in zuranolone's prospects for approval as a treatment for MDD, representing:

> This year and quarter have been marked by significant progress for Sage. We recently announced that following a pre-NDA meeting with the FDA, we and Biogen plan to submit an NDA for zuranolone in MDD in the second half of 2022, with an additional associated submission in PPD in the first half of 2023. We're pleased that we've reached alignment with the agency and believe we have a clear path for this submission. This brings us one step closer toward our goal of helping patients suffering from MDD and PPD.

162. According to Greene, the Company "met with the agency in early 2020 and designed 3 distinct Phase III studies, 2 in MDD and 1 in PPD." Elaborating, he indicated that "[t]he plan set in motion"—implying the conceivable involvement of the FDA—"was for a positive study from any 1 of the 3 paths to support an NDA filing and subsequent approval since it will provide the third positive pivotal study." Claiming that the pre-NDA meeting with the FDA "reaffirmed" the belief that the Company had sufficient data to support approval for MDD, Greene further explained:

> Based on the positive results from the WATERFALL study, we believe that we have the necessary data to submit an NDA for zuranolone. And we're delighted that our recent pre-NDA meeting with the FDA reaffirmed that belief. And now, in fact, we have 4 positive studies: MDD-201B, ROBIN, WATERFALL and the Shionogi Phase II study. The data we have generated in clinical development to date support our belief in the overall benefit risk of zuranolone.

163. He also reiterated that Sage did "not believe CORAL efficacy data will be required for the MDD filing pathway," indicating it instead would "contribute to [the] overall safety database regardless of the outcome of the primary endpoint." As he noted, zuranolone's approval prospects were favorable because "the totality of data" showed that "zuranolone has consistently demonstrated rapid and sustained reductions in depressive symptoms and a well-tolerated safety profile without the adverse events that are often associated with discontinuation of standard of care ADTs"—shorthand for antidepressant treatments. And he again positively described Sage's interactions with the FDA, indicating: "We've had a highly productive and transparent relationship with the agency and look forward to continuing to engage with them as we begin the rolling submission for zuranolone planned to commence in early 2022."

164. In turn, Doherty addressed the change in CORAL's primary endpoint, noting that the change from baseline on the HAMD-17 scale "will be measured at day 3." Describing this change as an "update . . . in line with the goal of the study to demonstrate the rapid onset of zuranolone," he noted that "including a trial with a day 3 primary endpoint may be a useful complement to the broad clinical package for zuranolone."

165. Doherty also spoke positively of ongoing development of SAGE-324 and SAGE-718, referencing the KINETIC study in noting the "statistically significant correlation between TETRA [sic] scores and activities of daily living observed at every time point," and characterizing the result as "an important finding that demonstrates the reduction in tremor seen with SAGE-324 in the study translated to meaningful effects for patients."

166. During the question-and-answer session, an analyst requested insight into whether "the CORAL primary endpoint change" was "FDA-driven or Sage-driven," with Greene responding that the change indeed resulted from FDA "feedback," noting: "we sought overall feedback on the CORAL study, statistical analysis plan from the agency. And after that feedback, we selected . . . the day 3 endpoint as the key primary endpoint really to get back to the original idea of the CORAL study, which is to demonstrate . . . the rapid relief of depressive symptoms early in clinical trials." As Greene explained, Sage "already had the efficacy data in hand for filing," which "allowed us now to move the primary endpoint to CORAL II to day 3."

167. In response to a similar question, Greene emphasized that Sage's pre-NDA meeting with the FDA prompted Sage's shift in focus to the speed of zuranolone's effectiveness: "we believe after the pre-NDA meeting that we have, the package to file, so it was important for us to have day 3 reflect that rapid onset."

168. Another analyst pressed Greene for even more detail on Sage's communications with the FDA, asking whether, "in your more recent FDA conversations . . . have you talked at all about how these durability time points will be interpreted from a regulatory perspective," and inquiring whether "statistical significance" at later times was necessary: "I know there's the ZULRESSO AdComm precedent, but because postpartum depression is an acute indication and MDD has more chronicity to it, just kind of curious if you've got confirmation that statistical significance at these later time points isn't really a hurdle?" Greene responded directly: "the quick answer is clinical significance at the later third point is not required." Addressing the issue further, Greene represented that "[w]hat the agency and what physicians look for is consistent and durable impact without a rapid return to baseline," noting that out of 4,000 patient subjects, "we've seen rapid benefit at day 3 with continued benefit out to day 42, and again, on SHORELINE, even longer term feedback."

169. Reflecting on the dialogue, a different analyst was confused as to why Sage would not simply use already existing Day 3 efficacy and response data for the MDD NDA filing if "we knew all along that day 3 will show statistical separation," asking "[w]hy do you guys keep saying that we shouldn't—we don't need it," and "why change it so close to [the] rolling NDA [submission]?" In answering, Greene referenced Sage's extensive communications with, and guidance from, the FDA since 2020:

> I'll remind you that in 2020, our team sat down with the agency following a number of Phase III studies, one, recognizing that MDD was the major unmet need and, in fact, a growing unmet need. So we and the agency and others appreciated that we needed something in addition to the currently approved antidepressants where we haven't seen a change in benefit/risk in a long time, and designed the LANDSCAPE and NEXT programs, 2 MDD studies and 1 PPD study. And we highlighted, and this is going back to consistent with our guidance in January that we needed 1 more positive study to have the package to file. We've got that and more we got the Japanese positive study as well.
>
> So we sat down with the agency in our pre-NDA meeting and confirmed that, that data package was sufficient for filing and that another Phase III was not required. But there was a dilemma in front of us, as we highlighted. We had 2 ongoing Phase III studies. So we had what I thought was a very good open strategic discussion with the agency, which said like, 'CORAL's coming up, let's file for MDD.' We're going to include CORAL in the filing, but the efficacy data is not necessarily required to be positive to file.
>
> Now the change to day 3 will benefit us if, in fact, day 3 is positive, and we see benefit over the treatment course. Those data will be incredibly important to guide our medical affairs force, our sales force in educating physicians about the appropriate use of zuranolone, including the totality of data.

170. The November 2, 2021 statements, which were extensive, were materially misleading for many of the same reasons that previous statements were. But the November 2, 2021 statements introduced a new dimension to Defendants' fraudulent scheme: they changed the CORAL study's primary endpoint from Day 15—MOUNTAIN's unsatisfied primary endpoint, from years earlier—to Day 3, which Defendants knew zuranolone could meet. And they again invoked independently unverifiable discussions with the FDA in justifying this change, as they continued to claim that the

FDA was intent on approving zuranolone for MDD—despite failing to meaningfully discuss what FDA approval of Auvelity might mean for zuranolone's prospects. For example:

a. The Form 10-Q's disclosure on AXS-05, as in earlier Forms 10-Q, continued to reveal only that the drug was a potential competitor to zuranolone if both received FDA approval. In truth, however, Auvelity—as AXS-05 came to be known—was competing for FDA approval back then and much further along in the process, with more compelling evidence of long-term efficacy.

b. Among other representations, the November 2, 2021 press release indicated that interactions with the FDA "reinforced Sage's belief" that its clinical trial data "will be sufficient for Sage to file in MDD" and Greene repeatedly cited talks with the FDA, as the following reflects: (1) "We're pleased that we've reached alignment with the agency and believe we have a clear path for this submission"; (2) confirming that meeting with the FDA "reaffirmed" Sage's belief that it had sufficient data to support approval for MDD; (3) "we sought overall feedback on the CORAL study, statistical analysis plan from the agency," "[a]nd after that feedback, we selected . . . the day 3 endpoint as the key primary endpoint"; (4) "we believe that after the pre-NDA meeting that we have, the package to file, so it was important for us to have day 3 reflect that rapid onset"; and (5) "we and the agency and others appreciated that we needed something in addition to the currently approved antidepressants[.]" These representations were materially misleading because they again conveyed, falsely, that the Company's studies bore the FDA's imprimatur for almost-certain approval.

c. Additionally, linking the CORAL study's primary endpoint change to FDA discussions was also materially misleading, because, if anything, that change—which contemplated evaluating efficacy on Day 3 instead of Day 15—would undermine zuranolone's approval prospects, not enhance them. Indeed, Defendants were armed with information about MOUNTAIN's failure to show statistical significance at Day 15, so they altered the CORAL study to avoid the same outcome while concealing the true reasons for the modification. Thus, Doherty characterized this change as a

mere "update . . . in line with the goal of the study to demonstrate the rapid onset of zuranolone," and Greene added that "it was important for us to have day 3 reflect that rapid onset."

d. At the same time, however, Greene claimed: "the totality of data" showed that "zuranolone has consistently demonstrated rapid and sustained reductions in depressive symptoms"; "clinical significance at the later third point is not required" because the FDA looks for "consistent and durable impact without a rapid return to baseline"; and "we have, the package to file, so it was important for us to have day 3 reflect that rapid onset." Thus, according to Greene, the Company restructured the primary endpoint in CORAL to demonstrate what other studies had already shown: zuranolone's rapid effect. Despite that this was not true, Defendants continued to perpetuate these falsehoods.

171. As the market digested the information regarding Sage's previously undisclosed plan to change the primary endpoint of the CORAL study to Day 3 to focus on zuranolone's rapid onset, rather than its prolonged and durable efficacy (at or after Day 15), the stock price began a steady, multi-day decline after an immediate, single-day rise, of 7.8%, on November 3, 2021. Thus, while Defendants successfully staved off a precipitous stock price decline with confident statements that the FDA understood and appreciated the rationale behind the change to CORAL's primary endpoint, the broader market remained confused and unsure of how to appropriately assess the implications of that change or what it meant for zuranolone's FDA approval prospects as a treatment for MDD.

172. On November 15, 2021, Greene participated in the Stifel Healthcare Conference. In his opening remarks, Greene hailed "clarity with the agency for our filing path . . . for zuranolone," adding: "we feel like we've gotten real good strategic alignment with the agency and real good clarity on moving forward." He also spoke favorably of SAGE-324 and SAGE-718, noting Phase II studies were on track for both.

173. Immediately, the host asked Greene to discuss "CORAL and the recent change that you made at day 3," repeating questions from the November 2, 2021 conference call on "the thought process in changing the endpoint" and how the change impacts "how we should interpret data days 15 and 42." Greene reiterated his previous answer that Sage had "3 different Phase III studies, 2 in MDD, 1 in PPD that we believed [if] any one of which is positive gave us the filing package."

174. Again, however, the host asked "[t]he obligatory question on durability, day 42, how to think about those data, regulatory significance," raising the Company's experience with Zulresso in commenting that previously, with that drug, "the FDA was pretty agnostic to the reality that in one of those trials at day 30, actually placebo did better than drug." Reiterating a line of questioning from the November 2, 2021 call, the analyst noted "MDD has a greater chronicity to it than PPD" and asked: "how confident are you from a regulatory perspective that some of the Wall Street folks who say you need a p-value or you need better separation there are just kind of dead wrong in terms of what the agency cares about?"

175. As in previous discussions, Greene downplayed the correlation between zuranolone and placebo and invoked the "reverse placebo" characterization to describe the effect of zuranolone, claiming "there's evidence that these patients get better and stay better" and "that's what" the FDA and others, in actuality, are "looking for":

> What we're looking at and what medical folks believe and the agency believes is that if someone can get better and stay better, that's what we're looking for. Having a robust placebo effect, which we're seeing across all depression trials is a part of running depression trials. It's inappropriate to use the words, the drug loses effect. In fact, at day 42, we saw 86% of the day 15 effects. The drug is not losing effect, having low dose placebo narrows that. Now what we don't want to see and we're not seeing this is that someone gets better, they stay better at 15. And then as soon as they're off the drug, they quickly rebound back to baseline.

176. As for Sage's other two main drugs under development, Greene's comments were equally as positive. For example, as to SAGE-718, he stated: "if you think about what we saw with

Huntington's Disease, not only did they [patients] not get worse, they got better in 2 weeks, which is quite remarkable. We saw that repeating in Parkinson's." He added: "SAGE-718 is fundamentally overlooked in terms of the massive value it can create." Likewise, for SAGE-324, Greene expressed unqualified confidence:

> [R]ight now, we're initiating a Phase II study testing various doses and frequency so that we believe that in addition to that 35% to 45% decrease in essential tremor, which also led to an improvement of activity with daily living that we have a drug that people can take chronic. So that's what we're studying now. We're very confident based upon our read of the data that we'll get there. They'll have both efficacy and then the drug that someone can take chronically because it is a condition that requires chronic administration.

177. Although Greene made fewer statements on November 15, 2021 than on November 2, 2021, his representations were no less misleading. For example:

a. In response to a direct question on the change to CORAL's primary endpoint, Greene claimed that "3 different Phase III studies, 2 in MDD, 1 in PPD"—"any one of which," "i[f] positive"—supported the NDA filing. Consequently, Greene's answer confirmed that the endpoint change was merely corroborative of other information that was already sufficient for FDA approval, and he placed no significance on that change for any other purpose.

b. Greene also again invoked the "reverse placebo" characterization to describe the effect of zuranolone, claiming a "robust placebo effect" is present in all depression trials and that the FDA was most interested in seeing "if someone can get better and stay better . . . ." But that was a gross oversimplification that failed to take into account true long-term durability, emphasized in FDA guidance on developing treatments for MDD.

c. As for SAGE-718 and SAGE-324, Greene issued overly favorable statements. For SAGE-718, he claimed that patients suffering from Huntington's Disease "got better in 2 weeks, which is quite remarkable. We saw that repeating in Parkinson's." For SAGE-324, he claimed: "We're very confident based upon our read of the data that we'll get there [safe and effective chronic

dosing]. They'll have both efficacy and then the drug that someone can take chronically because it is a condition that requires chronic administration."

178. On December 1, 2021, Sage issued a press release, filed as an exhibit on Form 8-K, about the SHORELINE study in zuranolone. The release indicated that the majority of patients who received 50 mg of zuranolone, and responded to an initial 14-day course, received just one two-week course of treatment, and that nearly 80% received only one or two treatment courses in total. The release also indicated that the 50 mg dose was well-tolerated with an overall adverse event profile consistent with earlier data, identifying "somnolence, dizziness, sedation, and tremor" as examples of adverse safety effects. Greene commented favorably on the results:

> We believe zuranolone has the potential to offer an innovative treatment approach that may enable patients with MDD to experience reductions in depressive symptoms quickly, achieve related improvements in functioning and well-being, and maintain long treatment free intervals without the types of burdensome side effects that are often associated with discontinuation of standard of care antidepressants.

179. Also on December 1, 2021, Greene represented Sage at the Piper Sandler Healthcare Conference, at which he discussed the topline results of the SHORELINE study—specifically noting that the safety profile of the 50 mg dosage of zuranolone was "very much like" the 30 mg dose. He again also analogized the drug to a "Z-Pak if you've got a lower respiratory tract infection," adding: "It might work in 14 days. You might need to recourse." He also reiterated previous statements on interactions with the FDA, including that there were three pathways to approving zuranolone—"two in MDD and one [i]n PPD"— adding: "With the positive WATERFALL [trial results], we confirmed with the FDA in our pre-NDA meeting that WATERFALL plus the rest of the data was sufficient for filing [the NDA], so we're moving forward."

180. Responding to a question about what the "FDA [will] focus on" for approval, Greene repeated other comments regarding Sage's communications with the FDA, noting: "we know from discussions with the agency and as evidenced actually by the ZULRESSO AdComm, that what

they're looking for is a rapid response and a sustained response without rebound. So we do have that in all of our trials out at day 42." In fact, Greene represented that "both the physician assessment but, even more importantly, the patient-blinded assessment suggest that those on drug stay better and are statistically significantly better at day 42."

181. The December 1, 2021 representations were materially misleading, perpetuating the façade that zuranolone was safer and more effective than competing alternatives in treating MDD. For example:

a. Greene's comments that zuranolone was well tolerated, with mild side effects like "somnolence, dizziness, sedation, and tremor," provided only a partial picture of potential side effects that did not reveal the possible correlation between zuranolone and suicidal ideation. But use of zuranolone, like many antidepressants, was linked to suicidal ideation and self-harming behaviors at least to some degree. It was materially misleading not to disclose these significant adverse events.

b. Analogizing zuranolone again to a "Z-Pak if you've got a lower respiratory tract infection"—a characterization that Greene used previously, to describe the drug's rapid onset and ease of administration—continued to misleadingly portray the drug's efficacy, and thereby also understated the risks associated with FDA approval.

c. It was likewise materially misleading for Greene to reference "discussions" with the FDA, as well as Sage's previous experience with the Zulresso AdComm, to state that "what [the FDA is] looking for is a rapid response and a sustained response without rebound." Zulresso is a markedly different drug, administered intravenously as a 60-hour infusion in a formal clinical setting for the purpose of treating new mothers experiencing PPD. Zulresso was also unique because it was the first FDA-approved treatment specifically for PPD, which meant the FDA's considerations in approving the drug differed fundamentally from the considerations informing the approval process

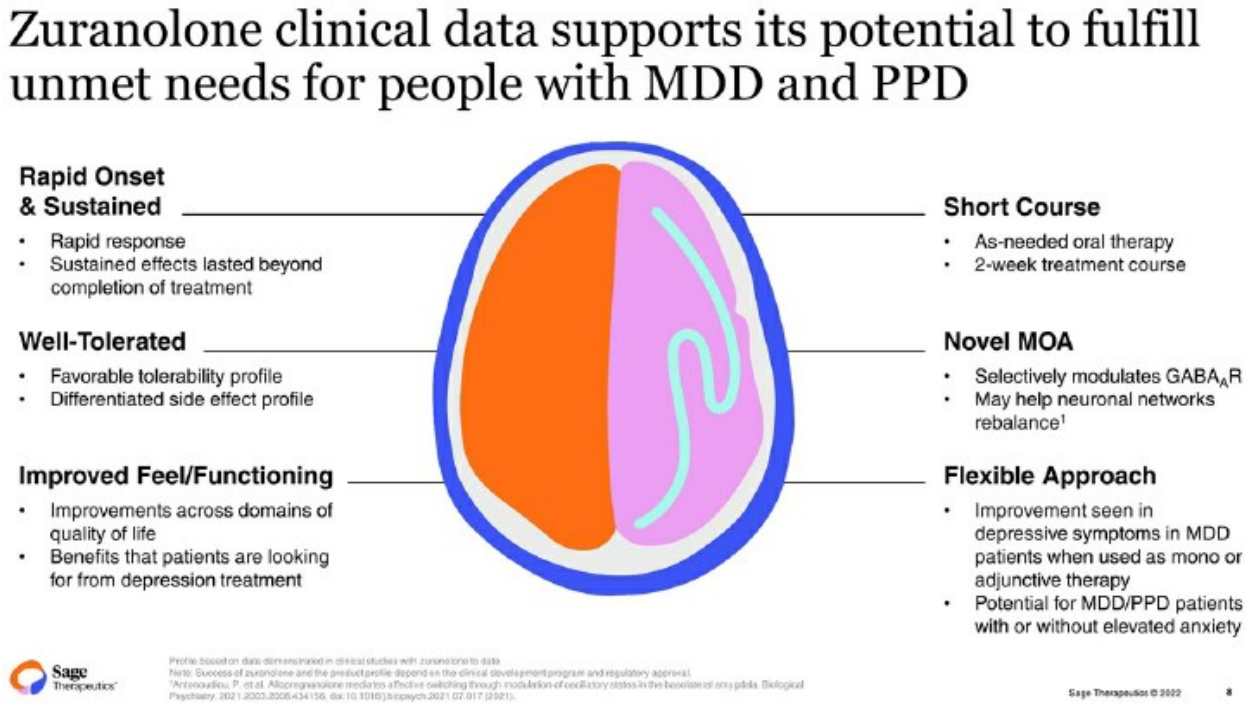
for zuranolone. It was thus unreasonable for Greene to reference Sage's experience with Zulresso in describing what the FDA would require in approving zuranolone.

d. Additionally, zuranolone never demonstrated statistical significance at Day 42 in MDD—only at earlier endpoints, such as Day 3, in WATERFALL, reported December 8, 2021—so it was improper for Greene to state that patients "are statistically significantly better at day 42." Specifically, in the December 8, 2021 press release, Sage announced that "[i]n the WATERFALL Study, a rapid onset of effect in HAMD-17 was observed compared to placebo as early as Day 3, reaching statistical significance, followed by a stabilization of depressive symptoms through the follow-up period." "Stabilization," of course, did not mean statistical significance vis-à-vis placebo.

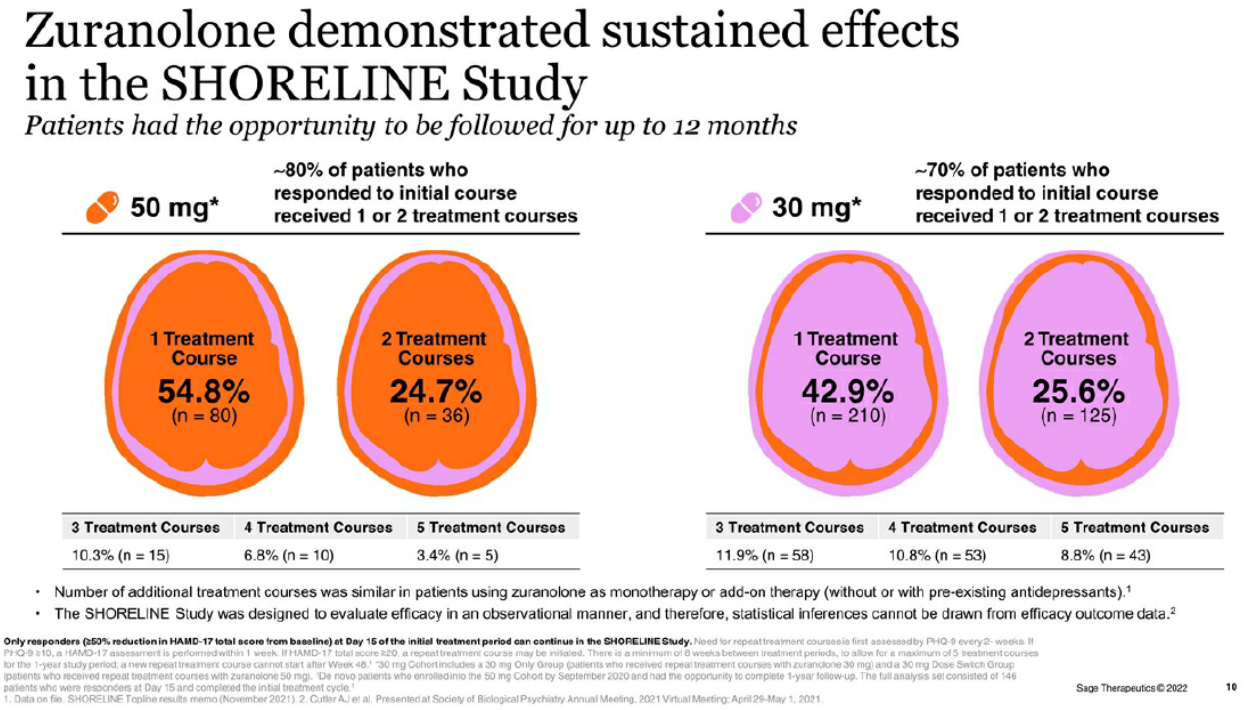
182. On December 17, 2021, Sage filed a shelf-registration statement on Form S-3, dated December 16, 2021, for the planned and continuous issuance of securities, including common stock, preferred stock, debt securities, warrants, and units. Because Sage lacked the ability to generate sufficient revenue to fund operations from the sale of Zulresso, the Company once again planned to leverage the issuance and sale of securities to raise funds if the need arose. The December 2021 shelf-registration was critical to those potential fundraising activities, because it streamlined and expedited the process by which the Company could sell securities to generate proceeds if necessary or desired. Key to promoting the sale of these securities, of course, were Defendants' materially false and misleading statements to the market during the Class Period.

C. From Early to Mid-2022, Sage Reports on the CORAL and SKYLARK Studies on Zuranolone, Continues to Promote SAGE-324, and SAGE-718, and Files the NDA for Zuranolone as a Treatment for MDD

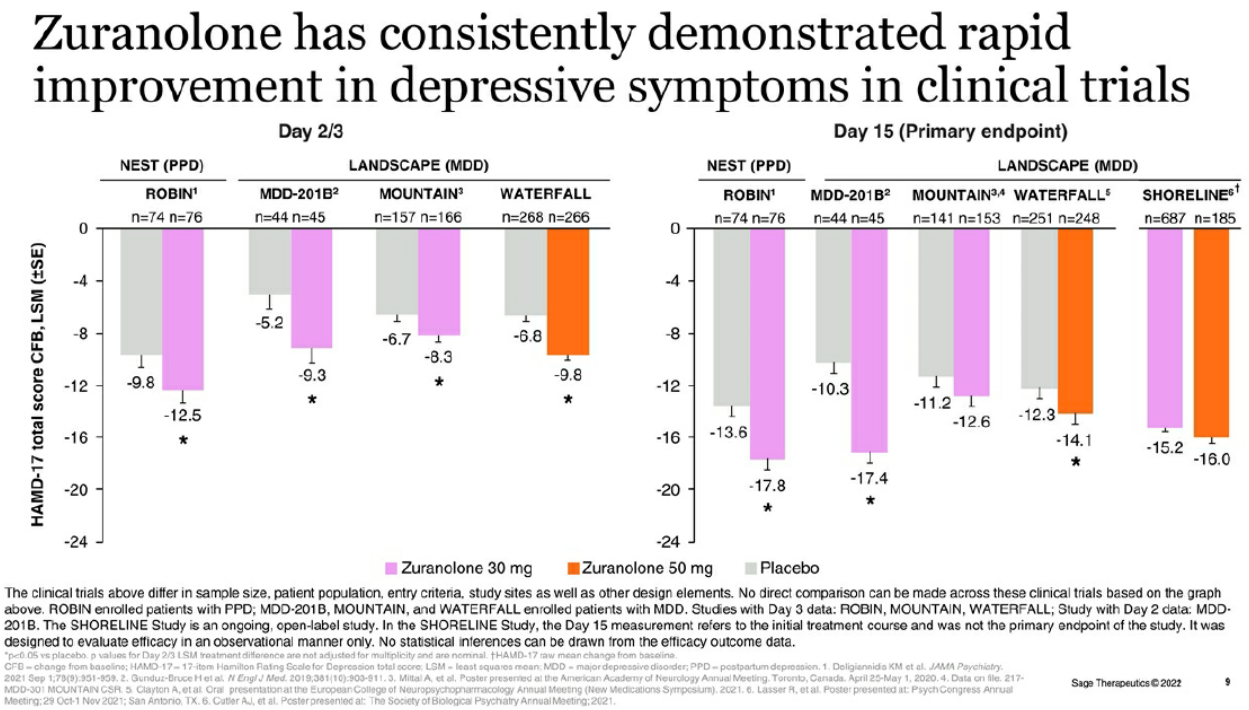
183. On January 10, 2022, Sage released presentation materials, filed as an exhibit to Form 8-K and available on the Company website, for the 40th Annual J.P. Morgan Healthcare Conference, scheduled to occur virtually. After detailing Sage's focus and mission, the materials contained the following slide on zuranolone:



184. That slide echoed Defendants' prior representations, indicating that the "[s]ustained effects [of zuranolone] lasted beyond completion of treatment[.]" Reinforcing this representation, the presentation emphasized that SHORELINE corroborated zuranolone's "sustained effects" over a 12-month period for most patients who received one or two treatment courses:



185. That slide, however, said that SHORELINE "was designed to evaluate efficacy in an observational manner," noting "statistical inferences cannot be drawn from efficacy outcome data." Yet the presentation favorably compared 30 mg and 50 mg doses of zuranolone versus placebo:



The clinical trials above differ in sample size, patient population, entry criteria, study sites as well as other design elements. No direct comparison can be made across these clinical trials based on the graph above. ROBIN enrolled patients with PPD; MDD-201B, MOUNTAIN, and WATERFALL enrolled patients with MDD. Studies with Day 3 data: ROBIN, MOUNTAIN, WATERFALL; Study with Day 2 data: MDD-201B. The SHORELINE Study is an ongoing, open-label study. In the SHORELINE Study, the Day 15 measurement refers to the initial treatment course and was not the primary endpoint of the study. It was designed to evaluate efficacy in an observational manner only. No statistical inferences can be drawn from the efficacy outcome data.

*p<0.05 vs placebo. p values for Day 2/3 LSM treatment difference are not adjusted for multiplicity and are nominal. †HAMD-17 raw mean change from baseline.

CFB = change from baseline; HAMD-17 = 17-item Hamilton Rating Scale for Depression total score; LSM = least squares mean; MDD = major depressive disorder; PPD = postpartum depression. 1. Deligiannidis KM et al. *JAMA Psychiatry*. 2021 Sep 1;78(9):951-959. 2. Gunduz-Bruce H et al. *N Engl J Med*. 2019;381(10):903-911. 3. Mittal A, et al. Poster presented at the American Academy of Neurology Annual Meeting, Toronto, Canada, April 25-May 1, 2020. 4. Data on file. 217-MDD-301 MOUNTAIN CSR. 5. Clayton A, et al. Oral presentation at the European College of Neuropsychopharmacology Annual Meeting (New Medications Symposium). 2021. 6. Lasser R, et al. Poster presented at: Psych Congress Annual Meeting; 29 Oct-1 Nov 2021; San Antonio, TX. 6. Cutler AJ, et al. Poster presented at: The Society of Biological Psychatry Annual Meeting; 2021.

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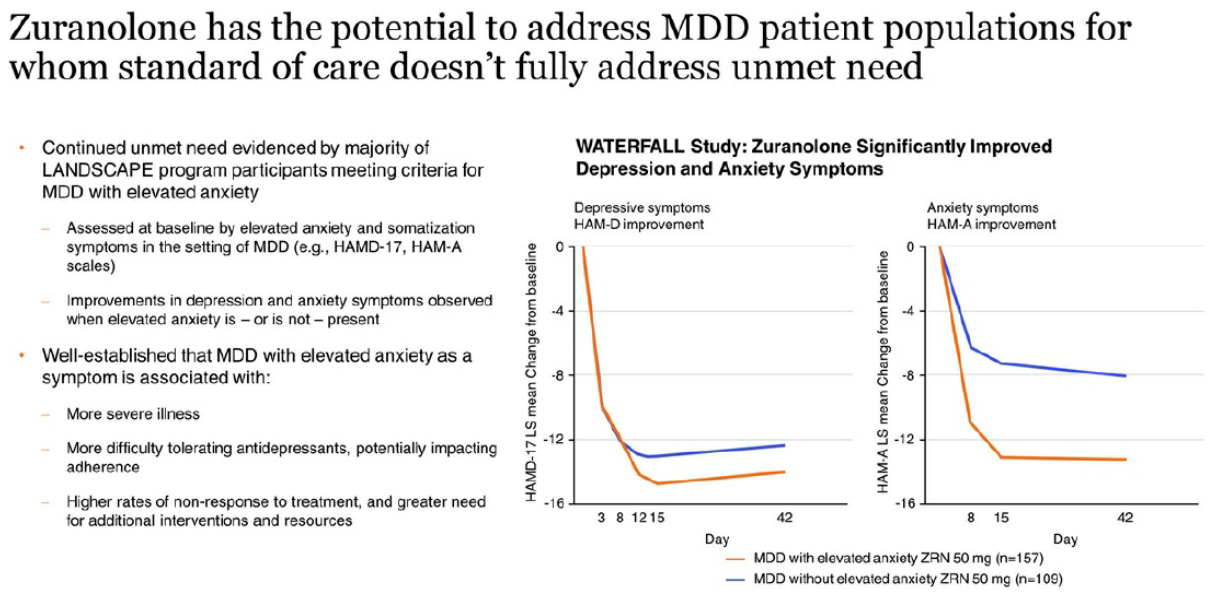
186. The presentation also highlighted zuranolone's effect on depression and anxiety, summarizing results from WATERFALL on patients with and without elevated anxiety:



Fava et al, 1997; Fava et al, 2006; Fava et al 2008; Ionescu et al, 2013, 2014; Papakostas et al, 2011
MDD with elevated anxiety is defined as a person with MDD who has a baseline HAM-A ≥20

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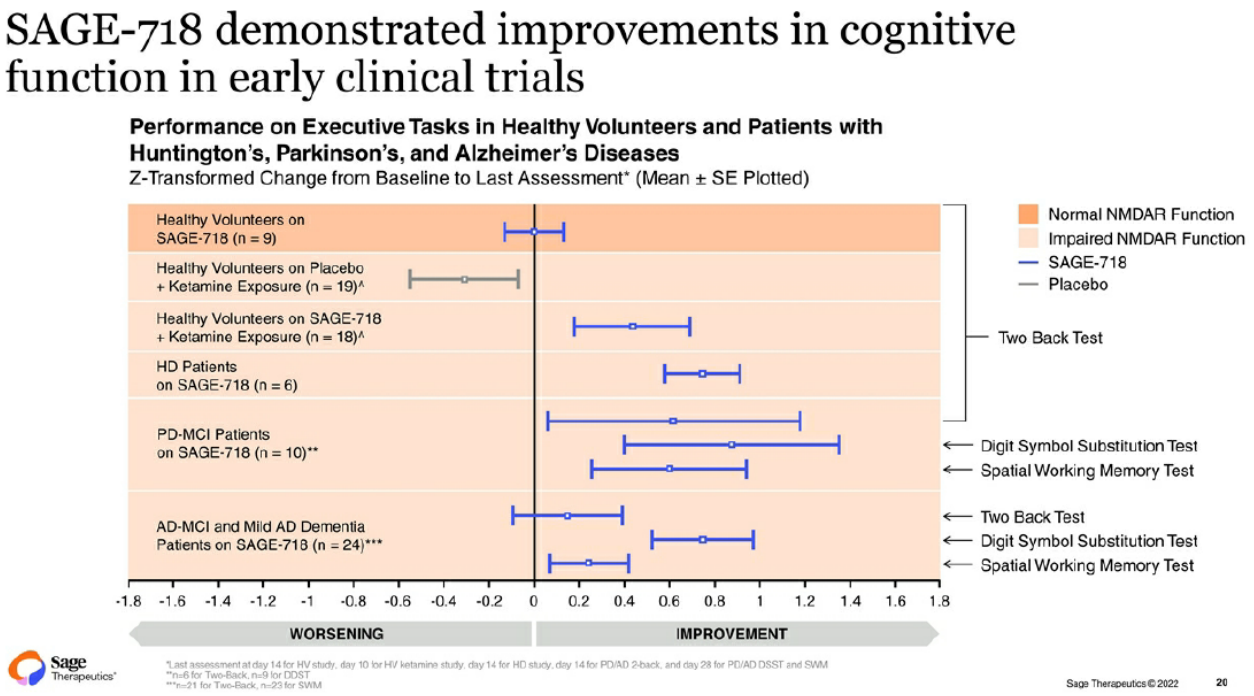
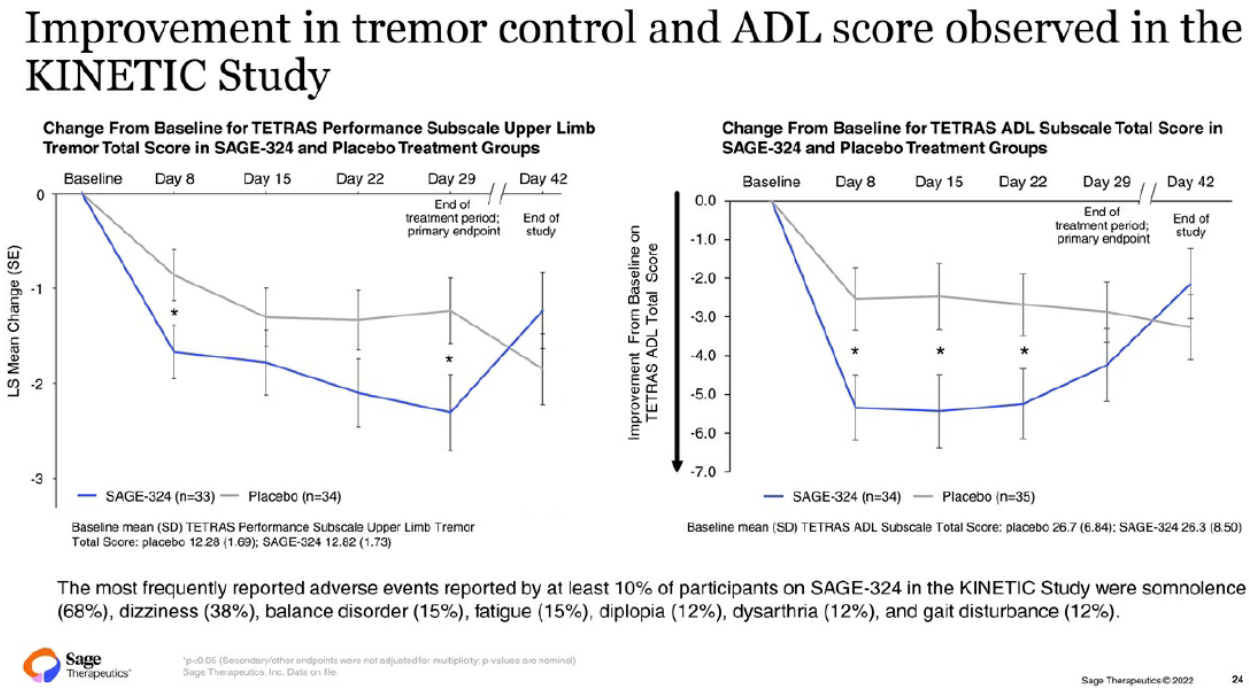
187. The presentation also underscored the significant market opportunity that developing an effective and widely-adopted treatment for MDD offered, estimating a population of 19.4 million adults with MDD who could potentially be candidates for zuranolone. This figure was consistent at least conceptually with Defendants' earlier representations regarding zuranolone's more lucrative market opportunity for the treatment of MDD.

188. Additionally, the presentation emphasized the efficacy of SAGE-718 and SAGE-324 and the corresponding market opportunities for Sage. For example, the presentation estimated the total market size of patients with Huntington's, Parkinson's, and Alzheimer's Diseases at over 140 million, and included the following slide promoting SAGE-718's "demonstrated improvements in cognitive function in early clinical trials":



189. The presentation then estimated that 136.4 million people suffer from essential tremor or Parkinson's Disease, noting "[i]mprovement in tremor control and ADL score observed in the KINETIC Study" of SAGE-324:



190. The representations and graphical depictions in the presentation, which promoted the efficacy of zuranolone, SAGE-718, and SAGE-324, were materially false and misleading because they overstated the efficacy of the drugs on the basis of data from studies that were not designed to determine long-term efficacy. Indeed, the SHORELINE study, in particular, was designed merely to "evaluate efficacy in an observational manner," foreclosing the ability to draw statistical significance from the results. At the same time, however, Defendants failed to temper their representations and graphical depictions to ensure that the investing public understood the entirety of the limitations of the studies so as to place adequate (or appropriate) weight on them.

191. The conference, which Greene, Iguchi, Doherty, and another representative attended, took place on January 11, 2022. Defendants reiterated information in the presentation, with Greene walking through particular slides in his opening remarks. In his opening comments, Greene cited slide 9 to emphasize "the rapid reduction in depressive symptoms we've seen with zuranolone in clinical trials in MDD and PPD to date," noting "significant reductions in depressive symptoms" after only "1 or 2 evening oral doses, and of course, robust reductions at day 15." And referencing

slide 11, he said that the "integrated analysis from [Sage's] completed pivotal placebo-controlled study in MDD and PPD" showed that "patients who received zuranolone demonstrated statistically significant improvements from baseline across assessments of well-being and functioning at both day 15"—"a day off drug"—and Day 42, as "compared to patients who received placebo."

192. Greene also compared zuranolone to FDA-approved treatments for MDD, citing slide 14 to show how its "potential benefit risk profile . . . may be distinct from current antidepressants" and stating: "The integrated response and discontinuation data generated with zuranolone studies to date shows higher response rates and much lower discontinuation rates." This statement conveyed that zuranolone was more effective than all FDA-approved antidepressants and exhibited lesser, or less pronounced, adverse events.

193. Greene also spoke favorably of Sage's two other main drug candidates. For example, citing slide 20, Greene noted that "SAGE-718 has demonstrated improvement on important test of executive function across multiple studies." Likewise, citing slide 24, Greene claimed that SAGE-324 exhibited "statistically significant reductions in tremor as measured by TETRAS upper limb tremor score . . . through day 29," and "statistically significant improvements in activities of daily living as measured by the TETRAS-ADL scale."

194. After Greene's introductory comments, the host asked for insight on "the rationale of moving the primary endpoint [for CORAL] from day 15 to day 3," and the importance of "later time points, day 15 as well as day 42, both to physicians and to regulators when it comes to assessing the profile of zuranolone." Greene built upon previous comments and effectively attributed the change to guidance that the FDA imparted in earlier communications.

195. Specifically, Greene represented that in 2021, "we had a good meeting with the FDA about the totality of zuranolone data," and, "in conjunction with the agency, designed 3 Phase IIIs, 2 an MDD called LANDSCAPE, 1 in PPD called NEST, that the agency guide us if any 1 of which of

these Phase IIIs was positive, we had a fileable package." He then claimed that Sage "had a meeting with the FDA" in late 2021, where "we confirmed that a positive WATERFALL presented a fileable package" and "confirmed that the agency would like us to start the rolling [NDA] submission."

196. Elaborating, Greene explained that setting the primary endpoint at Day 3 would allow CORAL to further confirm zuranolone's fast efficacy, again referencing the Company's experience with Zulresso to explain the FDA's thought process on the later time points. As he stated: "we know this from the ZULRESSO experience we had, where what regulators are looking for is consistency or durability of effect irrespective of what placebo does"—that is, lack of "a rebound of effect," where patients stay better through Day 42 and beyond.

197. The January 11, 2022 representations were largely materially misleading because they inaccurately portrayed zuranolone, SAGE-718, and SAGE-324. For example:

a. Greene's unqualified representation that the "integrated analysis" confirmed that "patients who received zuranolone demonstrated statistically significant improvements from baseline across assessments of well-being and functioning at both day 15 . . . and day 42" failed to place in context the appropriate implications and limitations of those results. The Company had never demonstrated statistical significance for zuranolone at Day 42 versus placebo in any MDD-focused study, so it was critical to explain the differences in evaluating patients' feeling, functioning, and other subjective measures in the PPD study from which that information originated. A footnote on slide 11 suggests that the statistically significant information was derived from the ROBIN study, the only cited study involving PPD: "Integrated analysis of SF-36 patient-reported outcomes data combined doses from the ROBIN Study, MDD-201B Study, MOUNTAIN Study (≥24 HAMD-17 subgroup), and WATERFALL Study, SF-36v2 = 36-Item Short Form Health Survey (version 2)." It was materially misleading to extrapolate statistical significance in MDD patients from a PPD study, or to otherwise imply that PPD and MDD patients and studies were situated similarly.

b. It was also materially misleading for Greene to reference FDA discussions to continue to intimate—as he and others had, previously—that Sage and the FDA jointly decided to shorten CORAL's Day 15 endpoint to Day 3. Again, Green emphasized zuranolone's rapid onset, claiming that the FDA "confirmed that a positive WATERFALL presented a fileable package"—which suggested that additional longer-term data was unnecessary, given that the primary endpoint of WATERFALL was Day 15.

c. Additionally, Greene's reference to Zulresso to bolster confidence in securing FDA approval of zuranolone was materially misleading for the same reasons it was on December 1, 2021: Zulresso is a fundamentally different drug, serving a particular purpose, for a narrow and well-defined patient population. In contrast to MDD, for which many commercialized pharmaceuticals were approved and prescribed for patients, there was no dedicated treatment available for PPD until Zulresso—so the circumstances under which Zulresso received FDA approval were substantially different than those facing zuranolone, which meant that the criteria for zuranolone's approval were materially different.

d. Similarly misleading was Greene's comment that "regulators are looking for" "consistency or durability of effect irrespective of what placebo does," which again downplayed the importance and implications of placebo-related performance, as compared to zuranolone's, in Sage's MDD studies. Greene's statement, however, was the latest in a long line of representations intended to minimize the relevance of placebo-related results. Referencing unverifiable information about the FDA—purportedly based on Sage's experience with the FDA in obtaining approval for Zulresso, and now in conversing with the FDA about zuranolone—instilled an aura of confidence, reliability, and credibility to Defendants' view of the lack of probative value of placebo-related performance in the Company's MDD studies.

198. Before the market opened on February 16, 2022, Sage issued a press release and held a conference call reporting the topline results of the CORAL study on zuranolone for treating MDD. According to the release, the study met primary and secondary endpoints: (a) "at the Day 3 primary endpoint, zuranolone 50 mg co-initiated with a standard of care antidepressant showed a statistically significant reduction in depressive symptoms"; and (b) for the key secondary endpoint, "zuranolone co-initiated with an antidepressant was statistically significant in reducing depressive symptoms compared to an antidepressant co-initiated with placebo over the 2-week treatment period[.]"

199. The release also noted that "[o]ther secondary endpoints demonstrated a statistically significant reduction in HAMD-17 score in the zuranolone co-initiated with ADT [antidepressant] arm compared to the ADT arm at Days 8 and 12, while Day 15 demonstrated numerical superiority and Day 42 showed equivalence." The release did not define the phrase "numerical superiority" or explain what "equivalence" meant, but nevertheless conveyed that zuranolone exhibited meaningful efficacy as compared to a placebo over the relevant periods tested.

200. The release prominently featured favorable statements from Greene, who lauded the study as a success and commented that the results, coupled with other data from the LANDSCAPE program, continued to position zuranolone for FDA approval for the treatment of MDD:

> We believe the CORAL Study is clinically meaningful and with the addition of this data the LANDSCAPE program now demonstrates zuranolone has three potential real world uses for the treatment of MDD. The LANDSCAPE data support zuranolone as a monotherapy, and since many people in the previously completed studies were already on maintenance ADTs, we believe our data also support zuranolone as additive therapy. The CORAL Study further supports the use of zuranolone to accelerate the benefit of conventional ADTs in treating MDD with a well-tolerated safety profile," said Barry Greene, Chief Executive Officer at Sage. "Including the CORAL Study, zuranolone now has six positive clinical studies, and we remain on track to start the rolling submission for a New Drug Application in MDD early this year with completion targeted for the second half of 2022.

201. Statements in the February 16, 2022 press release regarding "numerical superiority" and "equivalence" resulting from the CORAL study of zuranolone again understated the importance

and implications of the placebo-related data. Now, however, zuranolone was also evaluated against a competing MDD antidepressant (co-initiated, and thus administered, with placebo). Consequently, statements that misleadingly downplayed the importance of placebo also minimized the importance of the co-administrated ADT involved in the study. In fact, Greene's takeaway—that CORAL and the other LANDSCAPE studies evidenced zuranolone's viability as a "monotherapy" or "additive" treatment—disregarded the coalescence of effect between the CORAL study's arms as time went on.

202. The premarket conference call, held on February 16, 2022 after Sage issued the press release, also addressed CORAL's topline results. Seventeen analysts attended the call, and Greene, Benecchi, Doherty, and Investor Relations Officer Rubinstein participated on behalf of Sage. Sage also disseminated presentation materials, referenced during the call.

203. In his prepared comments, Greene reiterated CORAL's topline results, including that "zuranolone co-initiated with standard-of-care antidepressants or ADTs met the primary endpoint," "demonstrating a statistically significant reduction in HAMD-17 scores at day 3 . . . [as] compared to standard-of-care antidepression co-initiated with placebo." He also indicated that the key secondary endpoint was met, with "a statistically significant improvement in depressive symptoms . . . over the 2-week treatment period," which, in other words, meant that "zuranolone showed continuous benefit over the treatment period." He noted that "no new safety signals [were] attributable to zuranolone."

204. Beyond merely reciting the topline results, however, Greene again recounted Sage's interactions with the FDA. Noting that those communications gave the Company "confidence" that it had the data necessary for approval, he indicated that changing CORAL's primary endpoint to Day 3 was useful to confirm zuranolone's rapid efficacy and distinguish it from other forms of treatment for MDD. As he represented:

> [F]ollowing our pre-NDA meeting with FDA in late 2021, we confirmed our belief that we had the data needed to submit an NDA for MDD for zuranolone. Given our confidence in the data package to support the filing, we announced that the primary

> endpoint in the CORAL Study will be measured at day 3 because we believe that demonstrating rapid reduction in depressive symptoms at day 3 is an important differentiator and informs potential real-world use of zuranolone.

205. In his own remarks, Doherty reiterated aspects of the results, repeating performance data for zuranolone and adding that "adverse events reported in the study were mild or moderate in severity, consistent with previous data in the LANDSCAPE program"—and noting, "importantly, there were no signals for increased suicidality or withdrawal symptoms in the study." Doherty also emphasized zuranolone's "rapid and sustained efficacy."

206. Analysts inquired about how to interpret the CORAL study in assessing zuranolone's durability, given that zuranolone and a placebo were administered with an approved ADT drug—and both arms demonstrated similar efficacy at Day 42. Greene responded that "seeing separation out of day 42 is not something we expected"—an answer Doherty endorsed, stating "we are not surprised to see equivalen[ce] out at that time point."

207. Claiming that "expectation bias is pretty significant" because doctors and patients in the study knew each arm involved administering "an active drug," Greene explained that "real-world antidepressants actually do start kicking in" at Day 42 and represented that zuranolone's "rapidity of effect"—"particularly" for "MDD [patients] with elevated anxiety"—is "a real differentiator" as compared to other drugs. Yet later in the call, Doherty explained that equivalence at Day 42 did not undermine zuranolone's efficacy, claiming CORAL showed "a combination of efficacy for both the agents"—zuranolone and ADT, co-administered—that was "not unexpected," because "you would expect to see equivalen[ce] out at later time points like day 42."

208. Exploring the issue of durability further, an analyst asked about zuranolone's "value proposition" since "a key point of debate around these results like others [is] that you have statistical significance at earlier time point yet again, but not later." Again, Greene highlighted the rapid and sustained effect of zuranolone, noting, by comparison, that "it takes 6 to 8 weeks for people to see

benefit" from existing MDD drugs, patients often "drop off" of those drugs before then "because of side effects," and "the average course of [existing] treatment is 7 weeks per year" or more.

209. Benecchi echoed these comments when asked about the real-world use of the drug, describing as "really remarkable" the prospect of pairing a traditional ADT with zuranolone, given zuranolone's "sustained or durable effect over time" and "safety profile." He also noted—as Greene had earlier in the call, and the press release indicated—that zuranolone offered the added benefit of exhibiting efficacy specifically, and uniquely, for "MDD [patients] with elevated anxiety." In fact, Greene separately "highlight[ed]" that "in patients with MDD with elevated anxiety where standard of care does not work very well, it's well documented, we work particularly well."

210. Later during the call, Benecchi addressed the size of the patient population suffering from "MDD with elevated anxiety," noting it ranges from "54% to 66% of [MDD] patients cited in [the] studies" to "in excess of 70%" of MDD patients "in the real world, as you talk to practicing clinicians . . . ." Thus, he claimed, zuranolone "for the first time, gives [clinicians] the opportunity to treat a patient with MDD with elevated anxiety in a way that provides that rapid and durable effect over time through a short course without the stigmatizing side effects of sexual dysfunction and weight gain that they see with other ADTs."

211. Additionally, Greene and Doherty confirmed that CORAL's primary and secondary endpoints were derived from Sage's statistical analysis plan in evaluating zuranolone, developed in consultation with—and approved by—the FDA. In response to another question on the implications of CORAL on "regulatory approval," Greene indicated that "after our pre-NDA meeting" in 2021, Sage concluded that it "had the fileable package to move forward with" and then "confirm[ed] that with the agency," deciding "with Biogen, [and] the agency to have CORAL . . . show the rapidity of effect when co-initiated with an antidepressant." Providing a "remind[er]," Greene explained that the FDA was instrumental in determining the timing and sequence of the NDA:

> [W]hen we met with the agency, they were very helpful in guiding us, suggesting that, look, we've got 2 outstanding Phase IIIs, one in MDD, one in PPD. Let's complete the MDD study, include that in the filing and file for MDD. And then once you complete the PPD study, file for PPD. And the window is such that we might be able to kind of launch both indications at the same time.

212. Ultimately, an analyst noted Sage reported "86% efficacy retention at day 42" in the WATERFALL study, asking "what's the efficacy retention here for CORAL" and "how does that affect regulatory approval?" Claiming Sage "didn't calculate it in this study" (meaning CORAL), Doherty represented that the "response retention would actually be over 100%" in terms of absolute scores because patients "continued to improve over the duration of the study." In this way, Doherty again distinguished the efficacy of zuranolone-plus-ADT versus placebo-plus-ADT, trying to explain that Day 42 equivalence did not mean both arms in the CORAL study performed similarly from an efficacy or durability perspective—but, rather, that zuranolone performed demonstrably better.

213. Lastly, when asked if there was "any imbalance" in total adverse events between the two arms in the CORAL study and any incidence of suicidal ideation, Doherty confirmed there was "[n]o signal for increased suicidal ideation in the study across either arm," adding: "So in that sense, balanced across arms."

214. Many of the February 16, 2022 representations advanced the materially misleading portrayal that FDA approval of zuranolone for the treatment of MDD was all but assured, and that the CORAL results—which themselves were supposedly unnecessary for approval—substantially reinforced that conclusion. For example:

a. Greene's continued reference to non-public communications with the FDA in justifying the approach to CORAL continued to mislead investors. This time, he represented that Sage, Biogen, and "the agency" decided "to have CORAL . . . show the rapidity of effect when co-initiated with an antidepressant"—again, giving undue credence to the study design and structure, which investors would understand resulted from consulting the FDA.

b. It was also materially misleading for Greene to again claim, by implication if not expressly, that the FDA had somehow verified that Sage had developed sufficient evidence to support zuranolone's approval, "following [the] pre-NDA meeting with [the] FDA in late 2021 . . . ." According to Greene, that meeting ultimately led Sage to conclude "that we had the data needed to submit an NDA for MDD for zuranolone," and that "[g]iven our confidence in the data package to support the [NDA] filing," Sage changed the primary endpoint for CORAL "because we believe that demonstrating rapid reduction in depressive symptoms at day 3 is an important differentiator . . . ." The implication that changing CORAL's primary endpoint stemmed from discussions with the FDA, and that "demonstrating rapid reduction in depressive symptoms at day 3" was corroborative of other support already assembled for the NDA, misleadingly expressed that the FDA had assured Sage that evidence of longer-term efficacy was unnecessary in granting approval of zuranolone for MDD.

c. Defendants' use of the terms "numerical superiority" and "equivalence" were materially misleading, in the absence of any explanation of what those terms meant in the context of the CORAL study. In the absence of an explanation, investors were left to independently divine the meaning of these terms and accept Defendants' portrayal that zuranolone performed better than the competing study arm at least until Day 42, after which patients purportedly maintained the benefit.

d. At the same time, Greene and Doherty again downplayed the implications of the performance of the competing combination of antidepressant and placebo in the CORAL study, variously claiming "seeing separation out of day 42 is not something we expected" and "we are not surprised to see equivalen[ce] out at that time point." But these statements were inconsistent with others, in which Defendants said "it takes 6 to 8 weeks for people to see benefit" from existing MDD drugs—which suggested that equivalence would not occur if zuranolone had long-term efficacy. Indeed, combining zuranolone and a traditional antidepressant would amplify efficacy six weeks out, when the effect of the other drug would typically begin.

e. Doherty also exaggerated the magnitude of the patient response rate when he claimed that the "response retention would actually be over 100%" because patients "continued to improve over the duration of the study." Of course, patents in the competing arm—of antidepressant and placebo—exhibited a similar response, which is why there was equivalence at Day 42. Yet he and Benecchi tried to pivot, claiming zuranolone was particularly effective for patients with elevated anxiety—a subsection of MDD patients who typically experienced complications with traditional antidepressant treatments, which proved ineffective for them.

f. And, as on previous occasions, Greene claimed "no new safety signals [were] attributable to zuranolone," and Doherty noted there was "[n]o signal for increased suicidal ideation in the study across either arm . . . ." Even then, however, a question mark loomed over zuranolone's safety profile, which the FDA later confirmed in its public review when granting approval for PPD.

215. In response to premarket news on February 16, 2022 as to zuranolone's "equivalence" to placebo at Day 42 in the CORAL study, and resulting concerns about the durability of the drug, Sage's stock price declined substantially and continued to slide on elevated volume. All told, the stock price dropped from a close of $43.50 per share on February 15, 2022 to $33.58 per share on February 17, 2022—an aggregate overall decline of 22.8%. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
Feb. 15, 2022	$43.00	$44.06	$43.00	$43.50	345,600
Feb. 16, 2022	$36.25	$38.20	$35.30	$35.91	3,357,500
Feb. 17, 2022	$35.76	$35.76	$33.47	$33.58	2,071,300

216. Nevertheless, the stock price remained artificially inflated, as the market took into account Defendants' positive statements on zuranolone—including the purported limited relevance and consequence of equivalence to placebo in the CORAL study.

217. Before the market opened on February 24, 2022, Sage issued a press release (attached as an exhibit to a Form 8-K filing), and held a conference call with investors and analysts, reporting and discussing financial results for the fourth quarter and full year ended December 31, 2021. Sage

also filed its 2021 Annual Report on Form 10-K. The Form 10-K, which Greene and Iguchi signed, contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-K is accurate and non-misleading.

218. As the following excerpt reflects, the Form 10-K continued to address Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition, but provided an update:

> In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which has previously received Breakthrough Therapy designation for MDD, but the expected Prescription Drug User Fee Act, as amended, or PDUFA, target action date of August 2021 has been delayed.

219. The press release identified "key 2021 highlights" for zuranolone, SAGE-718, and SAGE-324, providing detail on clinical trials for those drugs and the planned NDA for zuranolone. The call was more comprehensive, involving five Sage representatives—Greene, Iguchi, Benecchi, Doherty, and Rubinstein—as well as 13 analysts.

220. In opening comments, Greene emphasized Sage's focus on positioning zuranolone to treat people with MDD and elevated anxiety, noting that subset of MDD sufferers is underserved and "up to 2/3 of people with MDD experience elevated anxiety symptoms . . . ." In his own remarks, Doherty noted that "WATERFALL and SHORELINE studies identified MDD with elevated anxiety at baseline as a subgroup that is particularly responsive to zuranolone"—a subgroup that he claimed "represents up to 66% of all MDD patients," who are "less responsive" to other treatments. They both emphasized Sage's focus on these patients throughout the conference.

221. Reflecting Sage's newfound shift to MDD with elevated anxiety, Greene also noted that "PPD often presents as depression with elevated anxiety." Yet he also recognized the difference between treating PPD and MDD, the latter of which usually involves longer periods of depression with more severe episodes. According to Greene, Sage "expect[ed] to see a statistical significant

difference at [day] 15" for PPD patients but not "necessarily" at Day 42 in the SKYLARK study, noting "[t]he key here is that these moms get better fast and stay better."

222. Asked about regulatory and commercial considerations regarding zuranolone, Greene responded that in 2021, the Company "reiterated the consistency of discussions we've had with the agency that WATERFALL constitute a filing package." Referencing the discussions, he added that, back then, "there were 2 outstanding studies, 1 in [MDD] CORAL and one in PPD SKYLARK, and they"—meaning, the FDA—"suggested and we agreed that we first filed an MDD, including the CORAL study and then with PPD, including the SKYLARK study."

223. But Greene also tied approval to zuranolone's efficacy in MDD patients with elevated anxiety, claiming Sage "did a retrospective analysis across our data and discovered that zuranolone was particularly useful in . . . MDD with elevated anxiety"—causing Sage to "prospectively" design "that subpopulation into the CORAL study." Noting that population is "about 2/3 of those annually diagnosed with MDD," he represented: "we have a very rich package for MDD with a pre-defined subpopulation [in] MDD with elevated anxiety" and "we're quite enthusiastic about the regulatory path forward." He then identified that cross-section of MDD patients as among the most important for zuranolone's commercial prospects.

224. When pressed on whether there were "specific factors that might prevent immediate zuranolone retreatment," "such as the average duration of maybe an MDD episode or more related to the pharmacology of the drug itself," Greene claimed that the drug would either work in two or three days or it would not, and retreatment would be "pretty straightforward in the real world."

225. The February 24, 2022 statements were materially false and misleading to the extent that they continued to convey that the FDA's involvement in meetings with Sage imbued confidence that Sage had appropriately designed zuranolone's studies, that those studies provided sufficient data for approval, and that approval was forthcoming as a result. For example:

a. The Form 10-K's disclosure regarding AXS-05, while updated to reflect the delayed target action date, failed to reveal material information necessary for investors to understand and contextualize the material risks that AXS-05 posed to zuranolone. Indeed, this disclosure—like similar, earlier disclosures—failed to provide meaningful detail on AXS-05's attributes and efficacy, prospects for FDA approval, and implications for zuranolone. But AXS-05's study design, potential FDA approval, and potential capture of market share all stood to influence zuranolone's approval, prospects, commercialization, and market success. Indeed, the generic and benign disclosure about AXS-05 in the Form 10-K continued to suggest that zuranolone's path to FDA approval for treating MDD remained unimpeded, confirming the potential relevance of AXS-05 solely as a competitor if both drugs ultimately received FDA approval.

b. Greene's repeated reference to meetings with the FDA misleadingly conveyed that the FDA blessed Sage's study design and NDA filing in MDD. In this instance, Greene claimed that the FDA "suggested and we agreed" to first file for MDD and then for PPD, which implied that the FDA had expressed confidence in the body of support that Sage developed for the MDD NDA. In this way, Defendants marginalized the importance of zuranolone's indication for PPD, given that, according to Sage, the FDA guided the Company to file for approval in MDD first.

c. Bolstering Defendants' efforts to instill confidence in zuranolone's prospects for approval in MDD, Doherty and Greene again emphasized its purported suitability for a subgroup of MDD patients with elevated anxiety. According to Doherty, WATERFALL and SHORELINE provided evidence of this application, and Greene claimed Sage "did a retrospective analysis across our data" to uncover this feature. These representations were intended to differentiate zuranolone from available MDD treatments, regardless of zuranolone's long-term efficacy and suitability for FDA approval.

226. On March 7, 2022, Greene represented Sage at the Cowen 42nd Annual Healthcare Conference. Almost immediately, the host inquired about the NDA, framing FDA approval for the treatment of MDD with zuranolone as a foregone conclusion based on the Company's prior public statements, as the following reflects:

> The first issue is the zuranolone MDD filing. Now that you have CORAL successfully behind you, statistical significance, it doesn't look like there's anything there that is necessarily going to be problematic for the filing. But folks want to know what's left?

227. Responding "we believe we're in very good shape," Greene referenced positive trial results and interactions with the FDA as support for that statement:

> So we're in really good shape with the planned rolling submission of the NDA for zuranolone, which as you know, we're developing for the treatment of MDD and PPD. If I just take a step back and set some context, we started last year highlighting that we had 3 ongoing Phase 3 studies, 2 in MDD and 1 in PPD, any one of which if positive, constitute a filing, a positive filing. With positive [WATERFALL] last year, we met with the agency in the fall for a pre-NDA meeting, a formal pre-NDA meeting. We confirm that [WATERFALL], [i]n fact, was the last remaining piece to start an NDA and we're in good shape to do that. And as you mentioned, having a positive CORAL as part of that NDA is very, very helpful and will be instrumental as we commercialize.

228. In fact, Greene referenced a previously non-public "Japanese study," conducted by Shionogi, that he described as "the only pure placebo-controlled study where zuranolone was studied [at dosage of] 20 and 30 milligrams and demonstrated clinically relevant and statistically significant improvement in depressive symptoms at day 3, 8 and 15 . . . ." When the host asked if "Shionogi is planning on presenting that [study] anywhere," however, Greene said he was unaware, commenting: "[i]t's really up to them to present as with many Japanese companies, they tend to be a little bit more conservative and really focus on kind of the regulatory focus." Yet that study—even if available—would not provide statistically significant evidence of zuranolone's long-term efficacy.

229. Following this exchange, the host asked for more detail on Sage's dealings with the FDA, asking "how much more follow-up from SHORELINE is required for the filing" and "[h]as

the FDA sort of come down and said, this is what we need x number of patients, x amount of follow-up from SHORELINE?" Greene again responded confidently, citing Sage's discussions with the FDA to support his favorable disposition:

> Well, we have the data to follow. When we met with the agency in the fall of last year, we confirm that the efficacy studies that we talked about, overall safety in over 3,500 patients was sufficient for filing. So we have the data we need to file right now. What's important is the FDA has communicated that real-world evidence increasingly plays a role as a component of regulatory decision-making. So we're confident that SHORELINE, which is the largest prospective natural study done to date in MDD really aligns with FDA's efforts to emphasize real world evidence, and it's potentially transformative in the treatment of depression. So we've got the data we need.

230. The host also asked about the long-term efficacy of zuranolone for MDD, inquiring about detail on "the type of patients that actually needed . . . episodic retreatment over the course of the year of SHORELINE versus sort of a redosing to get to remission[.]" In response, Greene confirmed that zuranolone exhibited efficacy for as long as a year, adding that "a majority of patients take [the] drug for 2 weeks and are better for a long period of time," later quantifying (in a different exchange) that he meant "over a year":

> [W]hat I can say is that in the 50-milligram cohort, the majority of patients who responded to the initial zuranolone treatment received only 2 courses across the entirety of the year, 80% only needed 1 or 2 week courses. So that implies that those that responded did well for a long period of time.

231. Confirming Greene's representation, the host commented: "it sounds like you're saying that the average time point of redosing is further out. It's not close into that original, it's further out." Green responded affirmatively: "We're not ready to present that, but that's a good inference from the overall data set." He also positively framed the possibility that the FDA might not hold an Advisory Committee meeting for zuranolone's NDA, saying: "Ultimately, it's an agency decision whether to have an AdComm or not. If they do decide to have it, we'll embrace it . . . ."

232. The host then inquired about SAGE-324, asking Greene: "How confident are you with the new sort of dose and administration schedule to—that this next data will generate a commercially viable profile?" Greene confirmed the Company's confidence, responding that Sage was "highly confident looking at the data that we'll have a dosing regimen that provides coverage for essential tremor without any tachyphylaxis with a profile that allows some to [sic] standard drug for long periods of time without discontinuation rates."

233. Finally, as the question-and-answer session came to an end, Greene expressed similar confidence in ongoing testing of SAGE-718. When the host referenced Parkinson's and Alzheimer's Diseases in asking "how much buy-in do you have from FDA on what the approvable endpoint for PD and AD cognition is," Greene responded: "we're very well aligned with the agency in terms of forging new pathways," "[s]o we're in good shape and moving forward."

234. Many of the March 7, 2022 representations were materially misleading when made. For example:

a. Greene's statements about the purported long-term efficacy of zuranolone, and the notion that short-term treatment with zuranolone typically put MDD patients in "remission," perpetuated Defendants' broad, continuing campaign to materially overstate the effectiveness and durability of zuranolone. In this regard, Greene claimed that the FDA signaled that WATERFALL, "[in] fact, was the last remaining piece to start an NDA" in MDD, adding that Sage had "the data we need to file right now." But he also implied that the as yet publicly undisclosed Shionogi study on zuranolone supported efficacy, notwithstanding his concession that that the study evaluated shorter periods that failed to address the long-term efficacy and durability necessary for FDA approval.

b. Greene also continued to claim that an FDA decision not to hold an AdComm would be a positive development, framing the issue thusly: "If they do decide to have it, we'll embrace it . . . ." These representations continued to improperly induce confidence in zuranolone's

FDA approval prospects as an indication in MDD, regardless of the implications of Auvelity's study design and parallel FDA approval process.

c. At the same time, Greene emphasized the efficacy of both SAGE-324 and SAGE-718, confirming that Sage was "highly confident" SAGE-324 could treat "essential tremor without any tachyphylaxis" and "well aligned with the agency in terms of forging new pathways" for SAGE-718 when asked about FDA-accepted study endpoints. Thus, despite Defendants' focus on promoting zuranolone, they continued to effusively describe Sage's two other main drug candidates.

235. On May 2, 2022, Sage issued a press release announcing the initiation of the rolling submission of the NDA for FDA approval of zuranolone for the treatment of MDD. According to the release, Sage expected to complete the submission for MDD in the second half of 2022, followed by an associated filing for PPD in the first half of 2023.

236. On May 3, 2022, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the first quarter ended March 31, 2022, and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed and which contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

237. As the following excerpt reflects, the Form 10-Q continued to address Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition, but provided an update:

> In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which had previously received Breakthrough Therapy designation for MDD, but the expected Prescription Drug User Fee Act target action date of August 2021 has been delayed. In April 2022, Axsome announced that it had received and agreed to post-marketing requirements/commitments proposed by the FDA with respect to AXS-05 and in May 2022, Axsome announced that it anticipates potential FDA action on its NDA in the second quarter of 2022.

238. The press release reported first quarter 2022 financial results, as well as quarterly business highlights regarding Sage's completed and ongoing clinical trials. The conference call, which 13 analysts attended, followed the issuance of the press release. Greene, Benecchi, Doherty, Iguchi, and Rubinstein attended on behalf of Sage.

239. In his opening comments, Greene again tried to differentiate zuranolone from existing treatments by focusing on MDD patients with elevated anxiety. In this regard, he claimed that "zuranolone's mechanism of action is distinct from current antidepressants," noting "MDD studies to date . . . have included both patients with elevat[ed] anxiety as a symptom of their depression and those without symptoms of anxiety"—meaning "zuranolone may be well suited to address a clear unmet need for people with MDD regardless of their baseline anxiety symptoms."

240. In one of his comments, Doherty also emphasized zuranolone's application to patients with elevated anxiety, but linked Sage's confidence to discussions with the FDA regarding PPD. Referencing "conversations with the FDA to date" regarding zuranolone's prospect of approval for treating PPD, he "point[ed] out that because PPD often presents very similar to MDD with elevated anxiety, we are encouraged by the positive results we've seen in patients with MDD presenting with elevated anxiety as a symptom of the depression in the LANDSCAPE program."

241. During the question-and-answer session, an analyst inquired about SAGE-718 and its "potential dosing regimens" given "results in both Parkinson's and Alzheimer's suggesting a durable benefit beyond the dosing period." Greene responded that SAGE-718 "will be chronically dosed," but added: "we don't see any kind of tolerability challenges or tachyphylaxis that would warrant any kind of periodic dose or dose disruption"—conveying that the drug did not lose efficacy over time.

242. The focus then shifted to zuranolone, with an analyst asking about possible regulatory "restrictions around when a patient can be redosed." Greene replied that patients experienced fewer

adverse events from redosing, claiming: "We have not seen any additive safety with retreat. In fact, of the adverse event numerically, [it] actually goes down with each and every course."

243. Another analyst asked about "the timing of PPD and MDD approvals" and whether the FDA might approve zuranolone for PPD before MDD, to which Greene replied that Sage was "very much aided by our strategic discussion with the agency in the fall of last year"; "we had alignment with the agency that we needed one more positive study" and WATERFALL was it; and "the strategic discussion said, let's file MDD first . . . and then file PPD . . . after that."

244. Many of the May 3, 2022 representations were, in large part, materially misleading. For example:

a. The Form 10-Q's description of AXS-05, which now revealed that Axsome "anticipate[d] potential FDA action on its NDA in the second quarter of 2022," continued to omit material information about AXS-05, and the risks, if approved, to zuranolone and Sage. As time went on, however, the risks that AXS-05 posed to zuranolone intensified because every step closer to FDA approval was—at least potentially—a step backwards for zuranolone's competing, yet less-promising, NDA for approval in treating MDD.

b. Additionally, Defendants repeated many of their earlier representations, which were materially misleading. Greene again referenced the FDA in claiming "we had alignment with the agency that we needed one more positive study," indicating WATERFALL was it. And Doherty emphasized zuranolone's purportedly unique effectiveness in MDD patients with elevated anxiety, claiming that "PPD often presents very similar to MDD with elevated anxiety . . . ." By linking PPD to MDD, he once again sought to instill confidence in zuranolone's prospects of approval for MDD because the FDA was far more likely to approve zuranolone for PPD—which, until then, had only one dedicated and FDA-approved medication, Sage's Zulresso, whereas MDD had many.

c. Also misleading was Greene's effort to distinguish zuranolone's "mechanism of action," claiming it "is distinct from current antidepressants" and thus could satisfy an unmet need in treating MDD. But zuranolone's mechanism of action remained untested, and competing drugs—such as AXS-05, which was nearing FDA approval—had proven effective. In fact, Auvelity, as it would come to be known, worked as rapidly as zuranolone and demonstrated statistically significant improvement in depressive symptoms—and thus efficacy—for longer periods.

d. Finally, Greene reiterated that Sage had not identified any issue with loss of effectiveness of SAGE-718, expressing unqualified confidence that it was not an issue when he said "we don't see any kind of tolerability challenges or tachyphylaxis . . . ." These representations were materially misleading because they suggested that the Company had already confirmed the efficacy of SAGE-718, despite the need for further and more comprehensive, and better structured, testing.

245. On May 4, 2022, Sage issued a press release announcing its participation in the Bank of America Securities 2022 Healthcare Conference, indicating that a webcast of the presentation would be accessible at Sage's website at investor.sagerx.com. According to the release, a replay of the webcast would be available for up to 30 days after the event. When the conference took place on May 11, 2022, Benecchi and Robichaud participated.

246. The host first asked Benecchi to detail "the advantages" of "a rolling submission[.]" Benecchi claimed that "the rolling submission allows us to get our material in front of the FDA as soon as possible," prompting a question "about the potential for having an AdComm." Robichaud identified "durability" and "utility" as issues that "are probably . . . very important" to the FDA." He also explained that the FDA held a meeting for Zulresso, adding that zuranolone "is an oral therapy, not the IV therapy. So we expect that they may ask for the same thing."

247. Referencing the durability of zuranolone prompted the host to ask for more detail on how Sage viewed the drug, given that MDD is a "chronic disease" requiring extensive treatment:

> So maybe we can touch upon one of the points you just made about the benefits of zuranolone, which is durability. So do you think that the Street fully appreciates the drug's profile? So you are taking a more nuanced view to treating depression, right? So it's chronic disease, but you would like to treat it with first of acute therapy basically, right? So how does the question of durability get answered when you're trying to really treat people over spirts of time?

248. In response, Robichaud reiterated the Company message that a two-week treatment of zuranolone exhibited long-lasting efficacy for "the vast majority of patients," placing MDD in remission, while emphasizing that SHORELINE confirmed that one or two treatments sufficed:

> That's a fantastic question and one that we've evolved and learned as we've developed the molecule as well. We believe that patients don't want to be treated forever. You don't think of a depressed patient is now a press patient for life. We believe that depression is a disease, not who you are. What we found out through our clinical studies has been pretty consistent through all the clinical studies that we've conducted, is that a 2-week therapy of this in the vast majority of patients is all that is necessary to put their depression in some phase of remission, bring them to some level of relief from their depression. Will patients go back into depression, that possibility always exists.
>
> Because of that question, we started a very complicated and very thorough clinical study called SHORELINE, which is a study that looks at if patients need to be redosed over the course of a year. And we allowed patients to be doses many times as necessarily during the course of the year. And we'll probably talk about it more in depth. But in general, patients in that entire clinical study required only 1 or 2 doses over the course of an entire year. So it's obvious to us that patients don't want to be treated chronically for a year, 2 years or longer on therapy, especially therapies with side effect profiles that aren't necessarily attractive to most patients. And what we found out in that study is they don't need to be. The vast majority of patients require 1 or 2 doses or dose regimens of the 2 therapy.

249. Benecchi adopted and endorsed that response, representing that zuranolone offered some patients the opportunity to resolve depressive episodes almost immediately after treatment—for example, "within 3 days"—and offered others long-term relief without "perpetual therapy":

> There are patients that are incredibly troubled by their MDD and they're looking for solutions. And for many patients, sometimes that solution is something that they can take and they can know within 3 days or so that the medication is going to deliver what they want.
>
> In other cases, it's to have the efficacy and to really experience it without the stigmatizing side effects associated with other therapies like sexual dysfunction and

> weight gain. And sometimes, as Al mentioned, it's the opportunity to take a therapy to experience the relief and then not need to redose or retake the therapy for an extended period of time so they can get back to living the lives that they want to live in the absence of needing perpetual therapy.

250. Later, Benecchi reiterated this point when asked about feedback from physicians on zuranolone's drug profile:

> There's been a lot of sameness in this space and the mentality has been treated to fail. The opportunity to send someone home with a product that they know in 3 days works, and that they can take over a short course that has lasting effect, as Al mentioned, with respect to the SHORELINE data with 80% of patients effectively being able to go 1 year, which has 2, 2-week courses without the tolerability profile that you see with other therapies like sexual dysfunction and weight gain. It's a profound game changer for them.

251. He also expressed optimism when discussing the market for zuranolone, calling the market "incredibly large" in terms of patients, prescriptions, and clinicians writing prescriptions. He estimated the number of "unresolved" patients with MDD—a cross-section of those with MDD—at 6.8 million, in contrast to an estimated 500,000 women with PPD.

252. When the discussion turned to SAGE-718, the Company's representatives were no less positive. Robichaud set the stage by differentiating SAGE-718 from competing drugs, extolling the demonstrated efficacy of the drug for patients with severe cognitive disease and impairment:

> We've initiated a very thorough clinical examination of the effects of SAGE-718 in a number of different diseases associated with cognitive impairment, beginning with Huntington's disease, looking at Parkinson's disease as well as Alzheimer's disease. And just—I can briefly say that we've done open label studies in all of those diseases, and we've shown the effects of 718 on those 3 different diseases.
>
> And what we're seeing, thankfully, is a very similar effect on executive function and cognitive performance that is very much unlike what a lot of other companies are looking at today. We're looking at improving synaptic function and we're looking at improving the brain circuitry associated with cognitive decline. What we're seeing in a very short amount of time is improvements in, as I said, executive function and cognitive performance. That really encourage us about the utility of this molecule, not just any specific type of neurogenic disease but across a platform of diseases that have cognitive impairment as sort of a common alloy amongst them.

253. Many of the May 4, 2022 representations were materially misleading, as Robichaud and Benecchi continued to exaggerate zuranolone's efficacy. Acknowledging that "durability" and "utility" are "very important" to the FDA, Robichaud claimed that the Company's "clinical studies" were "consistent" in demonstrating that a default dose of zuranolone for just two weeks "is all that is necessary to put [patients'] depression in some phase of remission" in "the vast majority" of cases. Benecchi concurred, claiming a "short course" of zuranolone "has lasting effect" and obviates a need for the further treatments "for an extended period . . . ." And Robichaud added that SAGE-718 effected rapid improvements in "executive function and cognitive performance." These statements overstated and exaggerated the efficacy of zuranolone and, secondarily, SAGE-718.

254. Before the market opened on June 1, 2022, Sage issued a press release, and held a conference call, announcing favorable results of the SKYLARK study of zuranolone in PPD. On the call, Greene, Benecchi, Boyle, Doherty, and Rubinstein represented Sage, and 18 analysts attended. During the call, Doherty linked the positive results to the more lucrative MDD indication, claiming they "further validate findings from other studies with zuranolone across PPD and MDD, showing that patients . . . maintained" a response after treatment "had concluded."

255. As the call continued, analysts commented that "the MDD opportunity is substantially larger than PPD" and asked how the SKYLARK data might "impact the probability of zuranolone approval in MDD." Greene emphasized Sage's communications with the FDA, which "confirmed that with a positive WATERFALL [study], we had a fileable package for MDD," adding that "the agreement with the agency was to move ahead with a rolling submission for MDD," "include the CORAL data," and "then [make] an associated NDA filing with the PPD data."

256. Another analyst sought insight into "why you're seeing [zuranolone] work in both MDD and PPD, but seeing a larger effect size in the latter." Both Greene and Doherty denied that zuranolone worked more effectively for PPD than MDD, with Greene "emphasiz[ing] again that we

are seeing consistency of data in both PPD and MDD across 3,000 treated patients," and Doherty claiming "[t]he only difference is really in the triggering"—explaining that in PPD, "it's the changes in physiology associated with parturition and birth where it's going to be more variable in MDD."

257. The June 1, 2022 representations, which again linked zuranolone's efficacy in treating PPD to MDD, were materially misleading, because the two conditions required different treatment protocols and timing of effect. New mothers suffer from PPD, and in many instances, a short-term treatment is sufficient. By contrast, MDD, on the whole, can often be more extensive and severe, and may involve suicidal thoughts and behavior. For these reasons, zuranolone's rapid effectiveness in treating PPD would not necessarily have the same benefit for MDD patients, who required longer treatment or a more lasting effect. It was therefore materially misleading for Greene and Doherty to group together PPD and MDD when discussing zuranolone's efficacy and prospects for approval; zuranolone had a substantially higher possibility of receiving FDA approval for PPD, especially given the costs and complications related to administering Zulresso for PPD; and the PPD data and results could undermine approval for MDD, because PPD and MDD ostensibly required different treatment regimens and an approvable medication had to satisfy different needs.

258. On June 2, 2022, one day after announcing the SKYLARK study results, Sage issued a press release announcing its participation in the June 8, 2022 Jefferies Healthcare Conference and the June 13, 2022 Goldman Sachs Annual Global Healthcare Conference, indicating that a webcast of the presentations would be accessible at Sage's website at investor.sagerx.com. According to the release, a replay of the webcasts would be available for up to 30 days after the events.

259. At the June 8, 2022 Jefferies conference that Greene, Benecchi, and Iguchi attended, the host first focused on Sage's communication with the FDA, commenting "[y]ou guys have always been very confident that you're going to get approval" and asking: "what's been some of your interactions with the FDA" and what "makes you feel very confident that you're aligned in terms of

the path forward for this medication?" Greene was effusive, describing the FDA's eagerness to work with Sage and contrasting that enthusiastic response with his experience at other companies:

> I think we've been working with the FDA, as you pointed out, significantly through these process even from the days when we were trying to move [Zulresso] forward spoke with the FDA very early about this approach to treating depression and the difference between the standard of care that exists today, a rapid onset, short duration treatment and durability of effect. And they've been very excited about working with us to allow us to at least get the studies needed to demonstrate that and ultimately bring the data forward that would convince them this actually is a differentiated product. So it's been, I would say, I've worked at large pharma companies and has been very different from my experience in those avenues where the FDA is encouraged or really wanted to work with us. And the CORAL study came out of discussions with the FDA about what to do and how we wanted the use case scenario. So they've been working very closely with us to help us think about gathering all the data necessary to inform patients, caregivers and physicians, but how this dose—how this drug could be use in depression and postpartum depression. And that's been our goal ever since and that's why we've done all these different studies with these different end points is to try and give as much data as possible to inform how to treat depression in a way that is very different, that's been done for the last several decades.

260. The host then raised CORAL, acknowledging "it was a positive study," but noting "the original endpoint maybe it missed on"—evidently referencing Sage's decision to unexpectedly change the primary endpoint from Day 15 to 3—and asking how "the FDA interpreted" the data. Greene did not directly answer, instead representing that "the real goal of the CORAL study was to demonstrate rapid onset" when administering zuranolone with another antidepressant, "so the 3-day endpoint was really meant to demonstrate that and very robustly did."

261. The June 8, 2022 representations were, by and large, materially misleading, because Greene continued to disseminate misinformation to the market regarding zuranolone. Claiming that "the CORAL study came out of discussions with the FDA," Greene again focused on "rapid onset" as a way to bolster confidence in zuranolone's prospect for FDA approval for MDD. He reiterated that Sage changed CORAL's endpoint to Day 3 "to demonstrate rapid onset," separately explaining that the FDA has "been working very closely with us . . . ." Like previous misrepresentations, these

statements instilled a false sense of confidence in zuranolone's study design and data—confidence Defendants purposely sought to project by referencing non-public, and independently unverifiable, interactions with the FDA.

262. At the June 13, 2022 Goldman Sachs conference that Greene attended, Greene first addressed Sage's announcement, issued earlier that day by press release (filed as an exhibit to Form 8-K), that it would submit a single NDA seeking approval of zuranolone for MDD and PPD instead of first seeking approval for MDD and then PPD. As he explained, "accelerat[ing] the PPD aspect of the NDA" "simplifies the review process," which is "better for us" and "the agency . . . ."

263. Inquiring about the announcement, the host asked "[w]hat prompted the change" and whether the FDA was "receptive" to it, as well as whether filing a single NDA would "in any way strengthen or increase the opportunity here for approval." Greene claimed that "by combining MDD and PPD, we strengthened the totality of data, particularly given how strong the SKYLARK study was." According to Greene, doing so "greatly strengthens the overall package and kind of the timely probability of approval by having a totality of the data."

264. Again trying to differentiate zuranolone from available antidepressants, Greene later claimed that the drug "works particularly well in a group of patients where standard of care doesn't work that well," elaborating: "that's with MDD with elevated anxiety or as sometimes they're called anxious depression," and "those patients act a lot like the PPD patients."

265. Explaining that the CORAL study demonstrated durability of effect for zuranolone, Greene claimed that if the FDA ultimately chose not to convene an AdComm meeting, that would be a positive development: "they could decide that given the unmet need and given the benefit risk, then AdComm is not warrant[ed] to move forward for approval." Yet he noted that if the FDA held an AdComm meeting, it would ask if the "onset of action [is] fast" and about "the durability of effect."

266. The June 13, 2022 representations were materially misleading because they continued to spread falsehoods meant to conceal adverse information about zuranolone's approval prospects. For example:

a. Greene said that "combining MDD and PPD . . . strengthened the totality of [the] data, particularly given how strong the SKYLARK study was," but the SKYLARK study in PPD was of limited utility in demonstrating efficacy or durability in MDD. As a result, SKYLARK data could not overcome gaps and shortcomings in Sage's MDD data.

b. Greene also favorably framed the FDA's potential decision not to hold an AdComm, claiming "they could decide that given the unmet need and given the benefit risk, then AdComm is not warrant[ed] to move forward for approval . . . ." But that misleading portrayal—based on Defendants' nonpublic guidance from the FDA, which investors could not independently verify—did not begin to address the factors most important to the FDA in considering whether to approve zuranolone for MDD.

267. In this way, Defendants continued to mislead the investing public about zuranolone, knowing their falsehoods would remain concealed because the FDA, by practice and policy, would neither publicly confirm nor deny any of Defendants' statements—no matter how inaccurate.

D. For the Rest of 2022, Defendants Positively Portray Sage's Drugs Under Development, Announcing Completion of the Rolling Submission of the NDA for Zuranolone in December 2022

268. On August 2, 2022, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the second quarter ended June 30, 2022, and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed and which contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

269. As the following excerpt reflects, the Form 10-Q continued to address Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition, while failing to meaningfully describe how the approval of that drug might impact zuranolone or otherwise have implications for the Company's business:

> In April 2021, Axsome Therapeutics, Inc. announced that the FDA had accepted and granted priority review to the NDA package for its NMDA receptor antagonist, AXS-05, which had previously received Breakthrough Therapy designation for MDD, but the expected Prescription Drug User Fee Act target action date of August 2021 has been delayed. In May 2022, Axsome announced that it anticipated potential FDA action on its NDA in the second quarter of 2022, which has not been updated.

270. The press release included a favorable comment from Greene, who said: "Based on the consistent clinical profile of zuranolone, we believe it has the potential, if approved, to address the significant unmet need for people suffering from MDD and PPD and we are working with a sense of urgency toward our goal of bringing zuranolone to them."

271. Participating in the conference call were Greene, Iguchi, Benecchi, Robichaud, and Rubinstein, as well as nine analysts. In opening comments, Greene reiterated that "the totality of the data generated with zuranolone support [its] potential . . . as a rapidly acting generally well-tolerated oral therapeutic to treat" MDD and "PPD with sustained effect." In turn, Robichaud represented that the SHORELINE study data "support our belief that zuranolone can have remarkable durability." He added that for patients re-treated with zuranolone in the SHORELINE study, "efficacy and safety outcomes were similar to those observed in the initial treatment course."

272. Greene then confirmed that Sage made the decision to discontinue the RAINFOREST study "in conjunction with the agency," but would provide data on RAINFOREST and REDWOOD in the NDA. When an analyst asked "how confident you feel about the regulatory pathway," Greene expressed unqualified confidence, adding "we feel very good about . . . the traction we have with the agency": "I would say we're highly confident in the interactions we've had with FDA, stemming

back to 2020 when we outlined the LANDSCAPE and NEST programs. We've confirmed multiple times with the agency, the totality of the data required for [the] NDA filing."

273. When pressed for more detail on whether Sage's "conversations" with the FDA have "been interactive relatively [in] real time," Greene confirmed "there's regular interaction and updates with the FDA"—"formal and then the informal kind of e-mail interactions"—answering "yes, there's been regular interactions and things are going well." Greene later framed positively the prospect that the FDA may not hold an AdComm for zuranolone, stating: "If they don't want an AdComm and it signals speed of approval, that would be great." Again, invoking discussions with the FDA—which investors and analysts could not independently verify, confirm, or assess—conveyed the misleading impression that Defendants had the inside track on the FDA's thinking, and that aggregate data from Sage's PPD and MDD studies almost certainly guaranteed FDA approval for MDD.

274. On August 9, 2022, Iguchi, Robichaud, and Benecchi participated in the Wedbush PacGrow Healthcare Conference. Robichaud discussed zuranolone's "beneficial effects on sleep architecture," noting "it has been consistent with all of our studies that zuranolone . . . improv[es] sleep in a lot of patients." He positively portrayed this as a "major side-effect" that was, in fact, favorable for patients suffering from depression.

275. On August 10, 2022, Iguchi, Robichaud, and Benecchi participated in the Canaccord Genuity 42nd Annual Growth Conference. In a report following the conference, Canaccord noted Sage was "confident on [its] regulatory strategy" for zuranolone, adding that "Sage appears very confident around its filing strategy for [zuranolone]"—leading Canaccord to write that Sage remains and "is significantly undervalued solely on the zura opportunity in MDD/PPD," with "no specific contribution from" other drugs in the development pipeline.

276. On August 19, 2022, Axsome announced the FDA's approval of Auvelity for treating MDD in adults. In its press release, Axsome indicated that the Auvelity "is the first and only rapid-

acting oral medicine approved for the treatment of MDD with labeling of statistically significant antidepressant efficacy compared to placebo starting at one week" and "sustained at all subsequent timepoints." As the release explained, Auvelity "was statistically significantly superior to placebo in improvement of depressive symptoms as measured by the change in the [MADRS] . . . total score at Week 6," the "primary endpoint" of the drug's GEMINI study. According to Axsome, Auvelity "uses the first new oral mechanism of action in more than 60 years for MDD."

277. The following month, at the Morgan Stanley Global Healthcare Conference held on September 12, 2022, Greene reiterated that lack of an FDA AdComm was positive: "If they don't do an AdComm and that represents a more speedy approval, that would be great." He also referenced Auvelity (not by name)—which received FDA approval weeks earlier—claiming "it highlights a profile like zuranolone" in terms of FDA approval for the NDA. This exchange began when the host noted "there was a recent therapy approved for [Axsome] for MDD," asking: "Does that approval change your view on the commercial potential for—or positioning of zuranolone at all?" Greene claimed—unequivocally—"[i]t doesn't," responding, in full:

> It doesn't. And I applaud [Axsome] for getting the drug approved. More options for patients are great. What [Axsome] to me signifies is yet another drug in the wave of getting patients better fast is good. They claim that patients are better in 1 to 2 weeks, which is fantastic, rather than waiting 6 to 8 weeks to get better. And we've already talked about this. The world of whether it's esketamine or psychedelic, get someone better fast without chronic treatment. But they had to get better fast. So I think it highlights a profile like zuranolone, which has been consistent now in 4,000 patients were more where after 2 evening doses of zuranolone, you feel better, take it for 2 weeks, get off drug, not wean off drug, stop drug and you feel better for long periods of time. The short line data, the largest natural study run is a good support of what this drug could do.
>
> That to me represents how the drug probably will behave in the real world, which is kind of an 80% response rate. And for those that responded, the majority didn't need another 2 weeks of drug for the full calendar year that we followed them, 80% required only 1 or 2-week course of treatment in the course of the year. So if you ask anybody living with depression, if they'd rather have 2 or 4 weeks of drug versus 365 days of drug, the answer is pretty self-evident.

278. The September 12, 2022 conference marked the first time during the Class Period that Greene or any other executive from Sage directly discussed Auvelity. But Greene's representations were materially misleading. For example, he spun Auvelity's approval as a positive development for MDD patients and also zuranolone. While the first was no doubt true, Auvelity's approval was, in every sense, detrimental to zuranolone's prospects for approval and, by extension, Sage's business. Despite Greene's denials, Auvelity of course threatened the commercial potential and positioning of zuranolone. Indeed, Greene conceded that Auvelity reportedly worked quickly, yet claimed that the drug "highlights a profile like zuranolone"—suggesting that Auvelity's approval actually improved zuranolone's likelihood of approval. Thus, Greene's statements maintained the artificial inflation in Sage's stock price.

279. On November 8, 2022, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the third quarter ended September 30, 2022, and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed and which contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

280. As the following excerpt reflects, the Form 10-Q continued to address Axsome and Auvelity (by referencing AXS-05) in a general way in describing potential competition, but provided an update to reflect that Auvelity received FDA approval:

> In August 2022, Axsome Therapeutics, Inc. announced that the FDA had approved AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with an FDA-approved antidepressant affecting norepinephrine and dopamine, bupropion, for the treatment of MDD in adults.

281. Attending the conference call were Greene, Iguchi, Doherty, Benecchi, Rubinstein, and another Sage representative, as well as nine analysts. In prepared remarks, Doherty emphasized

"the effectiveness and durability seen in our clinical trials in patients who are on zuranolone," citing the SHORELINE study as support and noting "zuranolone was generally well tolerated with safety profile seen in the SKYLARK and SHORELINE studies consistent with prior clinical studies."

282. During the question-and-answer session, Greene again associated the prospect that the FDA might not convene an AdComm as a sign of early approval, stating: "If the FDA decides not to have an AdComm as a signal of an earlier approval, we're certainly ready for that . . . ." In response to a separate question, he claimed that "[i]n meeting with the FDA, we agreed that the SHORELINE Study could serve as an understanding of long-term safety and retreatment needs."

283. The Form 10-Q's disclosure regarding AXS-05 was materially misleading, because it failed to reveal how FDA approval of that drug would reasonably impact zuranolone's prospects for FDA approval in treating MDD. Likewise, Doherty addressed zuranolone's purported "effectiveness and durability" without addressing qualities that AXS-05 exhibited, which evidently led to approval. In fact, zuranolone still lacked sufficient evidence of durability, and SKYLARK and SHORELINE could not provide it. Indeed, contrary to Greene's suggestion, SHORELINE was not designed to establish or even assess zuranolone's long-term statistical significance. Because an AdComm would provide Sage with an opportunity to address these issues, any decision not to hold one was, in fact, negative. Thus, the November 8, 2022 statements continued to deceive the market.

284. On December 6, 2022, Sage issued a premarket press release, filed as an exhibit on Form 8-K, announcing completion of the rolling submission of the NDA for approval of zuranolone. Sage and Biogen also held a premarket conference call on commercialization plans for zuranolone, which Doherty and Benecchi attended for Sage together with several Biogen executives. Speakers referenced presentation slides concerning zuranolone.

285. During the call, a Biogen executive noted "there have been no signals of suicidal ideation or symptoms of withdrawal" from zuranolone—a representation that Defendants adopted,

through their silence. Separately, Benecchi claimed "it's clear from the LANDSCAPE and NEST programs that the frequency of AEs [i.e., adverse events] does drop after the dosing period ends," claiming SHORELINE confirmed that retreated patients experienced "a reduction in frequency reported following a second or third dosing."

286. In turn, Doherty was asked "what in the zuranolone data gives you confidence that the efficacy is durable," to which he replied: "We're actually very confident in the sustained and durable profile of zuranolone," citing "the LANDSCAPE and NEST program[s]." Benecchi later said that submitting a single NDA for MDD and PPD "makes it a little more efficient for" FDA review, noting "we're very confident in the single filing approach . . . ."

287. The December 6, 2022 representations, which capped off the year, were materially misleading because they continued to deceive the market about the information reasonably necessary to secure FDA approval and obscured zuranolone's lack of proven durability. Doherty's statement that Sage was "actually very confident in the sustained and durable profile of zuranolone" simply was not consistent with the totality of MDD-related data, and the PPD studies could not change that.

E. Throughout 2023, Defendants Describe Favorable Developments Until the FDA Denies Approval for Zuranolone to Treat MDD in August 2023, Forcing Sage to Reduce Its Workforce and Restructure Operations

288. On January 8, 2023, Sage issued a press release announcing its participation in the 41st Annual J.P. Morgan Healthcare Conference, which occurred on January 10, 2023. On January 9, 2023, Sage made available presentation materials for use at the conference, which included a slide portraying that zuranolone exhibited "[s]ustained effects [which] lasted beyond [the] completion of treatment[.]" The presentation materials were similar to the materials that Sage issued on January 10, 2022 ahead of J.P. Morgan's 40th Annual Healthcare Conference. Sage filed the press release and presentation materials as exhibits to Form 8-K.

289. On February 6, 2023, Sage issued a press release, filed as an exhibit to Form 8-K, announcing that the FDA had accepted the NDA and granted "priority review" of zuranolone for MDD and PPD. According to the release: "Priority Review is granted by the FDA to applications for medicines that, if approved, would provide significant improvements in the effectiveness or safety of the treatment, diagnosis, or prevention of serious conditions." The release detailed the trial data included in the NDA submission:

> The zuranolone NDA includes data from the LANDSCAPE and NEST clinical development programs as well as a Phase 2 study of zuranolone completed by Shionogi in Japan in adults with MDD. The LANDSCAPE program includes five studies of zuranolone in adults with MDD (MDD-201B, MOUNTAIN, SHORELINE, WATERFALL, and CORAL). The NEST program includes two studies of zuranolone in adult women with PPD (ROBIN and SKYLARK).

290. On February 16, 2023, Sage issued a premarket press release (attached as an exhibit to a Form 8-K filing), and held a conference call with investors and analysts, reporting financial results for the fourth quarter and full year ended December 31, 2022. That same day, Sage also filed its 2022 Annual Report on Form 10-K. The Form 10-K, which Greene and Iguchi signed, contained similar misstatements and omissions as the press release and call. They signed SOX Certifications, representing that the Form 10-K is accurate and non-misleading.

291. As the following excerpt reflects, the Form 10-K continued to address Auvelity (by referencing AXS-05) in a general way in describing potential competition, but no longer mentioned Axsome by name:

> If approved, zuranolone may also face competition for the treatment of MDD from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion, an FDA-approved antidepressant affecting norepinephrine and dopamine, which such combination formulation was approved in August 2022 by the FDA for the treatment of MDD in adults.

292. In the press release, Greene referenced Sage's "NDA filing for zuranolone in MDD and PPD" and "promising and targeted pipeline" in representing that "this momentum puts us in a

position of strength as we kick off 2023 . . . ." The press release also represented that "[z]uranolone, if approved, could represent the first oral, short course (14-day) medication with rapid onset for MDD and PPD."

293. Attending the conference call were Greene, Iguchi, Benecchi, Doherty, Rubinstein, and Chief Medical Officer Gault as well as 17 analysts. Doherty emphasized zuranolone's "rapid and sustained reduction in depressive symptoms as early as 2 or 3 days" and "generally well-tolerated safety profile." Benecchi echoed that message, claiming "the opportunity in MDD is large with millions of patients not satisfied with current treatment options," citing zuranolone's purported rapid and lasting effect:

> This is why rapidity matters, both in terms of initiating a therapy as soon as patients show symptoms, as well as achieving the rapid improvement of depressive symptoms. The key takeaway here is a more rapid and sustained approach to treating a depressive episode may increase the likelihood of better symptomatic and functional outcomes. Given the rapid improvements seen in clinical trials to date, we believe that, if approved, zuranolone has the potential to provide a new treatment option to patients suffering with MDD, with the goal of helping them return to a state of well-being sooner.

294. Benecchi also claimed that zuranolone would satisfy "the unmet need" in treatments for MDD, stating: "Given the unmet need, we believe that zuranolone, if approved, is best positioned at launch for MDD patients requiring a first add or first switch therapy after continuing to experience depressive symptoms, following their initial treatment course, including patients who have tolerability issues or noncompliance with chronic therapy." Again referencing this "unmet need," he said "there's a high understanding of unmet need in and amongst the payers, and truly a perception that they need something that works quite differently than what they've seen historically."

295. Greene also claimed "[t]here's regular communications with FDA on data updates, including SHORELINE." When asked if Sage "still think[s] there's a possibility for an AdComm," Greene repeated the message he conveyed many times before, commenting "that's solely at the

discretion of the FDA" but "[i]f the FDA decides not to hold an AdComm and that's a signal of a faster approval, we like that too."

296. Greene repeated that line almost verbatim at the Cowen Health Care Conference on March 6, 2023, when he said: "if they don't do an AdComm as a signal of a rapid approval or even early approval, we'll take that too, and we'll be prepared to launch." At that conference, he also referenced "consistent" communications with the FDA as an indicator of confidence, stating:

> [T]there's a senior team that's been consistent from the beginning with us, that's been engaged.
>
> And even before I started as CEO, I read every regulatory communication. What I can say is all of the regulatory communications and minutes have been consistent from day 1. The FDA was really helpful with Sage designing the landscape in these programs and talking about the Phase IIIs.
>
> They were very helpful in helping to understand one of the Phase IIIs that was designed in REDWOOD that didn't need to get run based upon the SHORELINE data. So the communication with senior levels, medical reviewers and others has been consistent from the beginning.

297. Representations on February 16, 2023 and March 6, 2023 were materially misleading, because Defendants continued to conceal some of the most prominent risks facing zuranolone and instead sought to—and did—express and instill confidence using deceptive means. For example:

a. The 2022 Form 10-K's disclosure regarding AXS-05 remained materially misleading, because it failed to reveal how FDA approval of that drug would impact zuranolone's prospects for FDA approval in treating MDD.

b. It was also materially misleading for Greene to represent on both February 16 and March 6 that the FDA's decision not to hold an AdComm could signal faster or earlier approval, given the FDA's recent approval of Auvelity—a transformative, new MDD treatment that exhibited rapid onset and prolonged efficacy in ways that zuranolone had not.

c. Additionally, Benecchi's claim on February 16 that "[t]he key takeaway here is a more rapid and sustained approach to treating a depressive episode"—which he clearly implied zuranolone provided—merely added to the misleading effect of other statements made on that date.

d. Finally, Greene's March 6 description of extensive communications with the FDA at some of the highest levels—with "a senior team that's been consistent from the beginning," and "communication with the senior levels, medical reviewers and others"—only continued to instill confidence in Sage's approach and the likelihood of FDA approval. Once again, Greene even said that interactions with the FDA prompted Sage not to run REDWOOD, suggesting that SHORELINE was instead suitable (even if not absolutely necessary, given other comments about WATERFALL). These representations continued to mislead the market, which was forced to accept at face value the Company's characterization of its communications with the FDA.

298. Two days after Greene's appearance at the Cowen conference, Sage announced that the FDA would not convene an AdComm for zuranolone's NDA. The Company press release, issued on March 8, 2023, provided no insight into the FDA's reasoning or the implications for the NDA or the FDA's potential approval of zuranolone for either MDD or PPD. Given Defendants' previous statements, however, the market was certainly led to believe that the FDA's decision not to convene an AdComm could represent a positive signal that approval might come rapidly or earlier.

299. On March 29, 2023, Iguchi, Benecchi, and Doherty participated in the 2023 Stifel CNS Days Conference. The host asked Doherty to "speak to how the regulatory process is going for zuranolone," adopting Defendants' favorable outlook: "We're really surprised that there's not an AdComm. I mean, that's certainly a good thing. No AdComm, no priority review is usually great, but were you surprised?" Doherty responded positively, claiming "they've decided in this case that they don't need to convene an expert group of panelists from the outside."

300. Benecchi was similarly positive when discussing zuranolone's market opportunity, making two primary points in attempting to convey the drug's unique positioning: (1) "we're talking about 6.5 million people with MDD who are actively making treatment changes in a given year," and "the vast majority of those have failed one or more existing antidepressants"; and (2) "nearly 500,000 or so moms or one in eight live births, women that are suffering with PPD who very much acutely need something immediately that can help them get back on a course to well-being." As he explained: "Our ambition with zuranolone in MDD is to be the first data or first switch medication for those that are suffering with MDD" and the "first-line therapy" for women with PPD.

301. When the host noted "where Axsome's drug is being used right now," stating "it's all in TRD [treatment-resistant depression] and insurance companies," Benecchi said "zuranolone has shown itself to be a versatile therapy, either as monotherapy, as an adjunctive therapy, or as a therapy that can be co-initiated with other antidepressants," and never directly addressed Auvelity (by name or otherwise).

302. The March 29, 2023 representations were materially misleading. As Doherty framed the AdComm, the FDA purportedly concluded that "in this case" "they don't need to convene an expert group of panelists from the outside." The implication from that statement—and Defendants' previous representations—was clear: the FDA saw an unmet need in the MDD market; understood and appreciated zuranolone's profile, rapid onset, and durability; shaped the design and sequencing of Sage's studies, including the decision to terminate two studies (REDWOOD and RAINFOREST); and instructed Sage to file one NDA for both MDD and PPD, despite Sage's initial intention to file separate applications simultaneously. The market was thus led to believe that Sage had the inside track to FDA approval; and because Sage rarely discussed Auvelity, the approval of that competing drug was of little to no consequence. In fact, when asked about Auvelity, Benecchi was dismissive and instead mentioned zuranolone's purported "versatile" qualities.

303. On May 2, 2023, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the first quarter ended March 31, 2023 (attached as an exhibit to a Form 8-K filing with the SEC), and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed, that contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

304. As the following excerpt reflects, the Form 10-Q addressed Auvelity (by referencing AXS-05) in a general way in describing potential competition:

> If approved, zuranolone may also face competition for the treatment of MDD from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion, an FDA-approved antidepressant affecting norepinephrine and dopamine, which such combination formulation was approved in August 2022 by the FDA for the treatment of MDD in adults.

305. Again, the Form 10-Q's disclosure regarding AXS-05—which was identical to that in the 2022 Form 10-K—was materially misleading, because it failed to disclose information regarding the drug's potential adverse impact on zuranolone and Sage itself. Thus, despite Axsome's ongoing efforts to commercialize Auvelity and the serious threat that it posed to zuranolone's FDA approval, Defendants' disclosure of "AXS-05" remained the same.

306. Attending the May 2, 2023 call were Greene, Iguchi, Benecchi, Doherty, Rubinstein, and Gault, as well as 12 analysts. In opening comments, Greene indicated that because zuranolone's NDA "is under review by the FDA," "during this review period, we'll not be making detailed comments on the potential label, FDA interactions or other related topics for zuranolone."

307. Yet Doherty did just that, positively portraying ongoing discussions with physicians and others regarding "the unmet need in depression," noting that "physicians continue to highlight that the potential to achieve both a rapid and sustained effect matters deeply to them and remains critical to their patients" and representing that zuranolone satisfied that need. He claimed "[w]e have

received consistent feedback on what they consider the main strengths of the zuranolone clinical data," with "rapid onset of action seen in clinical trials" and "an improvement in depressive symptoms observed as early as day 3." But Doherty did not stop there. He added: "physicians note that this clinical profile has the potential to be particularly impactful if zuranolone is approved, given zuranolone's 14-day oral course of treatment."

308. In response to an analyst who found "it really striking" that Sage was "talking about positioning zuranolone as a first add-on antidepressant," Benecchi attempted to distinguish Auvelity in passing, claiming "[w]e've seen rejections and we've seen later line of therapy use"—while Sage intended zuranolone as a first-line or early treatment. Greene later called zuranolone "a completely new approach to [de]pression," which Gault endorsed, stating: "as a clinician that's treated patients with depression, the thing that really strikes me about the zuranolone data is the rapidity of the response and the durability of that response . . . ." Gault later added: "It's my lead proposition that zuranolone will be used as an add-on ahead of any atypical antipsychotics."

309. When another analyst asked for comment "on some of the recent ended [potentially branded] competitor launches and how you're picking up the learnings from those, both on the size of the market, [and] targeting prescribers," Greene confirmed: "we are paying close attention to all the new launches, whether it's migraine launches or depression launches. And we are grabbing a whole bunch of learnings from those." Benecchi agreed, referencing Axsome's Auvelity:

> [A]s you take a step back and you think about the launches, we pay, as Barry said, very close attention to all facets from the way that they target their customers, the size of the sales force, the tools and resources that they're using to effectively manage their launch all the way through to external media and how they're spending their media dollars. So, we have quite a close lens trained on the various competitors and how they're acting in the market.
>
> What I would take a step back and say is that the approval and initial use of other products is really an encouraging signal that both patients and clinicians are really looking for therapies that work. In the case of Axsome's product, it's a therapy that they are looking at because it has a new mechanism of action and works a little bit

> faster than maybe some of the other medications that have historically been available in the market for the last 30 years to 35 years. I think this really demonstrates that there's unmet need for new treatment options for the management of MDD. As you know, there still is no treatment, an orally available treatment for PPD, and there is significant need there for a product like zuranolone.

310. Additionally, Greene represented that Sage sought to "stay below [the] specialty tier" at "roughly around $10,000 per patient per year" for a 14-day treatment of zuranolone, if approved.

311. Many of the May 2, 2023 representations were materially misleading, because they conveyed the misimpression that zuranolone was well-positioned for FDA approval despite the lack of MDD studies demonstrating statistical significance to six weeks. Doherty referenced "consistent feedback" from physicians on "the main strength of the zuranolone clinical data," citing "rapid onset of action" and "improvement in depressive symptoms observed as early as day 3." Gault concurred, referencing "the rapidity of the response and the durability of that response . . . ." And Benecchi was again dismissive of Auvelity, purporting to describe its limited application in practice as a way to favorably distinguish zuranolone. These statements continued to conceal zuranolone's weaknesses, while omitting the substantial risks that Auvelity posed.

312. On May 3, 2023, Sage issued a press release announcing its participation in the May 10, 2023 BofA Securities 2023 Health Care Conference and the May 17, 2023 RBC Capital Markets Global Healthcare Conference. Iguchi, Robichaud, and Benecchi attended both conferences.

a. At the May 10, 2023 BofA conference, the host asked for Sage's "view on not getting an AdComm," to which Robichaud said: "As we had indicated in the past, we were agnostic to it." As Robichaud explained, "we look at it as sort of an affirmation that the data set that we've compiled and submitted to the agency has given them a sufficient data in order for them to review the drug and make a determination of whether not the drug should be approved or not." Benecchi and Iguchi also discussed "unmet need" for zuranolone, while Benecchi emphasized treating "MDD with elevated anxiety, which represents more than 50% of the population out there . . . who need a

new medication like zuranolone . . . ." Benecchi also represented that Sage sought to "stay under the specialty tier of $10,000 per year or less" for a 14-day treatment of zuranolone, if approved.

b. At the May 17, 2023 RBC conference, Robichaud discussed the FDA review process, indicating that communications were occurring "on a regular basis" and—despite the FDA's decision not to hold an AdComm—"everything is going according to plan," "things are going well with them," and "we don't see any problems right now." He added: "over the years of developing zuranolone from our early days, we've been working with the agency to create the LANDSCAPE and NEST programs around MDD and PPD, respectively, to allow us to gain the dataset that we always thought would be necessary for the industry review to be able to decide on whether or not to approve this drug." He further assured: "we're working very closely with them . . . ." Robichaud also noted that increasing the dosage of zuranolone from 30 mg to 50 mg presented no patient complications. In turn, Benecchi again claimed that Sage would target MDD "patients who need a first-add or first-switch medication."

313. Robichaud's positive statements on May 10 and 17 continued to conceal issues that Defendants faced in securing FDA approval for zuranolone for MDD, which deflected attention from the most prominent risks confronting the Company. Claiming that the FDA's decision not to hold an AdComm was "an affirmation that the data set that we've compiled and submitted . . . give[s] them [the] sufficient data . . . to review the drug" diminished the importance of that development, providing an unrealistic and favorable portrayal of the implications—which concealed that the most likely consequence was the FDA's denial of approval for MDD. Indeed, Robichaud was not the least bit negative, citing "regular" communications with the FDA while representing that "everything is going according to plan," "things are going well with them [the FDA]," and "we don't see any problems right now."

314. On June 12, 2023, Greene attended Goldman Sachs's 44th Annual Global Healthcare Conference. Almost immediately, Greene discussed zuranolone's rapid onset and efficacy, claiming "[a]fter 2 oral doses at night, those that respond report starting to feel better" and "then at day 14, those who respond continue to stay well." Emphasizing the "tremendous enthusiasm" from payers, he said the "unmet need is clear" and "[t]he unique product profile of zuranolone if approved in MDD and PPD is unique for them." During the conference, Greene repeatedly referenced the existence of data from over 3,500 patients in MDD and PPD to substantiate his representations regarding zuranolone's effectiveness and durability. Additionally, he claimed Sage sought to price zuranolone, if approved, "roughly under $10,000 per patient per year."

315. The June 12, 2023 representations were materially misleading because they continued to conceal the most prominent risks facing zuranolone while promoting its rapid onset and data set—despite Defendants' knowledge and appreciation that zuranolone's risk and benefit profile failed to meet or exceed Auvelity's in treating MDD. Indeed, contrary to Greene's account, the "unmet need" was addressed—at least to some extent—when the FDA approved Auvelity for MDD.

316. On July 25, 2023, Biogen reported financial results for the second quarter of 2023, reaffirming full-year guidance but emphasizing the prioritization of "high potential opportunities." According to Biogen, this approach required reduced investment in stagnant or low-growth products and a workforce reduction of approximately 1,000 employees (11% of its workforce), while shifting "resources to the areas of greatest value creation." Some analysts noticed that Biogen's demeanor had changed from the first quarter, pointing out that Biogen was uncharacteristically quiet about zuranolone in its quarterly press, including the second-quarter earnings call.

317. As a result of the increased uncertainty surrounding zuranolone arising from Biogen, which the market was continuously digesting as a partial disclosure of potential problems for Sage, Sage's stock price declined over several days. Sage's stock price ultimately declined by $9.27 per

share, or 21%, over several days—from $43.95 per share on July 24, 2023 to $34.68 per share on July 31, 2023—on elevated trading volume. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
July 24, 2023	$44.64	$44.73	$43.74	$43.95	559,900
July 25, 2023	$43.69	$43.82	$39.57	$41.84	3,198,800
July 26, 2023	$41.36	$41.67	$35.65	$36.21	3,802,900
July 27, 2023	$36.88	$36.99	$35.79	$35.80	1,500,800
July 28, 2023	$35.95	$36.08	$34.18	$34.96	1,938,700
July 31, 2023	$35.11	$35.64	$33.51	$34.68	1,776,800

318. On Friday, August 4, 2023, Sage issued an aftermarket press release announcing the FDA's approval of zuranolone for the treatment of PPD only. In the press release, Sage confirmed its receipt of a CRL in which the FDA denied approval of zuranolone for MDD and advised that additional studies were necessary to establish its efficacy. According to Sage: "The CRL stated that the application did not provide substantial evidence of effectiveness to support the approval of zuranolone for the treatment of MDD and that an additional study or studies will be needed." Consistent with its custom and practice, the FDA did not release the CRL publicly. Sage did not make the CRL available publicly, although there was no impediment to it doing so.

319. Given the significance of this revelation, some analysts following Sage issued reports almost immediately after this development, including the following:

a. In an August 6, 2023 report, RBC Capital Markets, LLC ("RBC") referenced the Friday, August 4 announcement, noting that zuranolone's "effect size was modest and durability had been mixed" and that "FDA draft guidelines call for some continued observation of drug-placebo differences over time even for rapid-acting antidepressants . . . ." The report sought "more details on the companies' Monday morning call," expressed an interest in evaluating the FDA's "review documents" when posted on the FDA-sponsored website at Drugs@FDA, and questioned "whether the greater-than-expected concern from FDA" about "somnolence AEs . . . further tipped

perceived risk/benefit equation unfavorably." Later, on August 31, 2023, RBC issued another report (detailed below), discussing serious safety concerns that the FDA identified in reviewing the drug.

b. In an August 6, 2023 report, Guggenheim Securities, LLC observed that "[t]he likely sticking point" regarding zuranolone's approval for MDD "was on durability of effect" in the WATERFALL and CORAL "studies and the failed MOUNTAIN study . . . where the separation from placebo was gone after treatment stopped . . . ." The report also stated: "The FDA likely failed to see a favorable risk benefit profile for zura without additional placebo-controlled durability data (beyond SHORELINE)."

320. On Monday, August 7, 2023, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the second quarter ended June 30, 2023, and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed, that contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

321. As the following excerpt reflects, the Form 10-Q continued to address Auvelity (by referencing AXS-05) in a general way in describing potential competition:

> Zuranolone, if approved for the treatment of MDD in the U.S., may face competition for the treatment of MDD from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion, an FDA-approved antidepressant affecting norepinephrine and dopamine, which such combination formulation was approved in August 2022 by the FDA for the treatment of MDD in adults.

322. By continuing to describe AXS-05 as a competitor after the FDA denied approval to zuranolone for the treatment of MDD, the Form 10-Q disclosure suggested that Sage might renew its efforts to obtain FDA approval for that indication. Sage's two other main drug candidates remained under development.

323. Attending the conference call were Greene, Iguchi, Benecchi, Gault, and Investor Relations executive Ashley Kaplowitz ("Kaplowitz"), as well as 17 analysts. Acknowledging that the FDA denied approval of zuranolone for MDD, Greene expressed disappointment "with the FDA's position in issuing the CRL" and said Sage was "reviewing feedback from the FDA and evaluating next steps," while Iguchi said "given the update relating to the CRL and [MDD], we are refining our strategy." As Iguchi later revealed, confirming that the lack of approval for MDD had fundamentally changed Sage's prospects and required the Company to shore up finances: "We'll be looking at a workforce reorganization and that's all with the goal of extending our cash runway."

324. Addressing the FDA's denial, an analyst asked "what happened during the review" if there were "[a]ny review issues that were discussed at the mid-cycle review that are now a focus of unresolved questions." Greene responded: "We learned late in the review cycle about FDA's view on approvability for MDD." Yet an analyst inquired about whether Sage ever had sufficient data for approval, noting "in guidance from [the] FDA, they talk about 2 drug placebo controlled studies that have to show duration of effect," and commenting: "you clearly had that in one of your studies, but it's not clear that you had that in a second study." Without denying the analyst's assessment, Greene noted that Sage had "6 of 7 positive studies" to support the NDA for MDD.

325. The additional detail provided on August 7, 2023 revealed that Sage's NDA for MDD likely lacked sufficient support to demonstrate durability, contrary to previous representations. Yet both Greene and Iguchi left open the possibility that Sage might seek FDA approval for zuranolone in MDD in the future. Nonetheless, August 7, 2023 was the first trading day after the revelation that the FDA had denied approval for MDD, and the market processed that information.

326. In response to this news, Sage's stock price opened at $18.80 per share on August 7, 2023—far below the closing price of $36.10 per share on August 4, 2023, before news emerged of the FDA's denial of approval of zuranolone for MDD. All told, Sage's stock price fell $19.35 per

share, or 53.6%, to close at $16.75 per share on August 7—on extraordinarily high volume of over 19.7 million shares traded, or almost 11.6 times the trading volume of 1.7 million shares on August 4, the previous trading day. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
Aug. 4, 2023	$36.00	$36.66	$35.63	$36.10	1,749,400
Aug. 7, 2023	$18.80	$19.53	$16.51	$16.75	19,740,300

327. Within three weeks, Sage was forced to execute a large-scale workforce reduction and so-called "strategic reorganization." In an August 31, 2023 press release, Sage announced plans to: (1) "[r]efine pipeline development efforts"; (2) "[i]mplement a ~40% workforce reduction designed to right-size the organization"; and (3) "[a]lign [the Company's] leadership team structure . . . ." As part of this reorganization, Robichaud and Doherty planned to leave Sage, and they soon did so.

328. Also on August 31, 2023, RBC issued a report on the FDA's review of zuranolone, indicating that the FDA review-related documents—albeit "heavily redacted, limiting interpretation to some degree"—"provide a glimpse into the sticking points for the Agency that led to the rejection in MDD." Among RBC's observations included in the report were the following:

a. The FDA identified troubling safety concerns with zuranolone as a treatment for MDD—not present in studies relating to PPD or the FDA's review of that indication—that likely contributed to denying approval for MDD. As RBC recounted, the concerns involved more extreme sedation and an increased rate of suicidality in MDD—not exhibited in the PPD studies—that may have caused Sage to focus primarily on PPD (and perhaps even join the indications together in one NDA, as Sage ultimately did):

> FDA expressed several concerns about zuranolone's safety profile which we believe likely influenced their benefit/risk assessment in the MDD indication. The Agency noted several instances of significant sedation or altered consciousness such as confusional state, including a ph.I patient at a dose/exposure ~30%-50% higher than the approved dose who had "a severe AE of unresponsive to stimuli 50 minutes after dosing" and was "rendered unconscious twice" and a second patient who was unconscious for nearly 5 hours (both received the oral solution formulation, which

> may have different PK properties). For PPD, while a REMS was seriously considered and heavily discussed around the sedative effects and driving risk, this was ultimately found manageable through labeling; it is unclear whether the potential necessity for a REMS in MDD and its commercial implications had ultimately led SAGE or partner BIIB to change their strategy last minute and focus primarily on PPD. FDA also noted a higher rate of suicidality in MDD which was not seen in PPD, though a closer look at the case narratives indicates causality from the drug is unclear.

b. The RBC report also indicated that Sage's public descriptions of zuranolone's safety profile was not necessarily consistent with information gleaned from the FDA's review:

> FDA's characterization of the AE profile does not appear completely aligned with SAGE's historical interpretations, as the company has indicated that there have been no signals of suicidal ideation or loss of consciousness events observed in the program—which may suggest FDA may not perceive the benefits, given uncertainties around durability (cited in the review document as the #1 key efficacy review issue) and effect size, as ever outweighing potential AE risks of the drug/class given intermittently in an MDD setting, even with additional data.

c. Additionally, the RBC report indicated that the FDA voiced concerns about the "size of the safety database" in 2021, noting it was unclear whether Sage addressed that issue:

> Interestingly, FDA did express concerns around the size of the safety database at one point in 2021, noting that SAGE would require an adequate number of subjects receiving zuranolone for 6 treatment cycles for a one-year period at the go-forward dose; it is unclear whether this was ultimately satisfied with the latest SHORELINE updates to an adequate degree (the review docs cite safety data from 37 patients at 50mg through 5 cycles).

d. As for the FDA's decision not to convene an AdComm for zuranolone, the RBC report noted that the "FDA seemed to suggest an AdComm was never considered because the drug was not first-in-class and there were no scientific/technical issues that would benefit from an AdComm discussion[.]" While not mentioned in the RBC report, the FDA's refusal to hold this meeting—which would have empaneled experts in the field to assess the unique benefits and risks of the medicine—could have been linked to the FDA's review and approval of Auvelity for MDD. By the same token, the FDA simply could have viewed zuranolone's mechanism of action and efficacy in MDD as not sufficiently novel to warrant AdComm review or involvement.

e. Lastly, the RBC report noted that the PPD portion of the NDA did not seem to raise any issues that seemed to require extended attention from the FDA and was uncontroversial:

> On the PPD front, nothing in the document that would change our commercial views or expectations: FDA seemed comfortable efficacy and durability were rapid and clinically meaningful, and had slightly fewer concerns on safety given likelihood of onetime use and lower possible suicidality risk.

329. The FDA review materials provided further insight into the FDA's concerns about the correlation between increased suicidality-related markers and zuranolone in treating MDD patients, as opposed to PPD patients.

a. In this regard, the review specifically detailed incidences of suicidal ideation (referred to therein as "SI") in the SHORELINE study, designated as 217-MDD-303:

> In Study MDD-303A, on-treatment, five subjects reported SI, two subjects reported suicide attempts (one of these subjects was also among the five who reported an SI AE), and one subject reported suicidal behavior; off-treatment, four subjects reported SI, two subjects reported suicide attempt, two reported intentional self-injury, and one reported suicidal behavior. In Study MDD-303B, one subject reported on-treatment suicide attempt and one subject reported off-treatment SI.

b. As the report indicated, "[i]n the MDD studies"—unlike PPD studies—there was "a slight imbalance of shift from lesser to greater SI in subjects in the zuranolone group both on- and off-treatment," all of which exceeded placebo (as the following snapshot from the report shows):

- On-treatment MDD-301B: 5/268 (2%) on zuranolone compared to 2/269 (1%) on placebo
- On-treatment MDD-305: 6/212 (3%) on zuranolone compared to 2/218 (1%) on placebo
- Off-treatment MDD-301B: 10/268 (4%) on zuranolone compared to 5/269 (2%) on placebo
- Off-treatment MDD-305: 6/212 (3%) on zuranolone compared to 4/218 (2%) on placebo

c. Accordingly, the report concluded the review noted, "[t]here was no signal for suicidal ideation and behavior in the PPD studies," but "there was a signal in the MDD studies" and the FDA could not "rule out an effect . . . ."

330. On September 6, 2023, Sage announced its participation in the September 13, 2023 Morgan Stanley 21st Annual Global Healthcare Conference and September 20, 2023 T.D. Cowen 3rd Annual Novel Mechanisms in Neuropsychiatry Summit.

a. At the September 13, 2023 Morgan Stanley conference, Greene confirmed that Sage was focused on launching zuranolone for PPD and cut spending on anything involving the MDD indication. Turning his attention to the Company's main drugs under development, he noted: "What we've seen thus far is that when orally taken SAGE-718 dramatically increases cognition in a very rapid period of time." He also noted that SAGE-324 effectuated "change in tremor amplitude," with benefits through 28 days at the maximum daily dose of 60 mg. And he indicated that pricing for zuranolone in treating PPD would rise above previously-guided levels, stating "previously, we highlighted that with MDD and PPD, that $10,000 was the ceiling specialty tier," but "I would not consider that on the table right now . . . ."

b. At the September 20, 2023 T.D. Cowen conference, which Iguchi, Benecchi, and Gault attended, Gault revealed that Sage still had not communicated with the FDA regarding the CRL or, more generally, the MDD denial. As to SAGE-718, Gault said that Sage was conducting three studies—two placebo controlled, and one open label—but noted that "the primary endpoint" for the 201 Study (DIMENSION Study) "is the Huntington's Disease Cognitive Assessment Battery, which is a battery of a number of different cognitive tests that test learning and memory" to measure change in function, but "hasn't been validated from a regulatory perspective . . . ."

331. Several of the September 13 and 20, 2023 representations were materially misleading. Greene's claims that "SAGE-718 dramatically increases cognition in a very rapid period of time," and that SAGE-324 effectuated "change in tremor amplitude" with benefits through 28 days, failed to appropriately convey drawbacks in the Company's study methodologies. In fact, Gault conceded that the Company had adopted a primary endpoint for a study of SAGE-718 that Defendants knew

was not "validated from a regulatory perspective"—meaning the FDA had not approved its use. Yet Defendants continued to speak positively, failing to publicly acknowledge problems inherent in the Company's testing methodologies.

332. On October 18, 2023, Sage issued a press release announcing that the FDA granted SAGE-718 Orphan Drug Designation, reporting: "Multiple clinical studies are ongoing with SAGE-718 across several disease areas . . . ."

333. On November 7, 2023, Sage entered into a sales agreement with Cowen for an "at the market offering" program to offer and sell common stock, having an aggregate offering price of up to $250 million, from time to time through Cowen. Sage also filed a prospectus supplement to its December 2021 shelf-registration statement, expressing the intention of engaging in additional stock sales to generate proceeds when desired. As the prospectus supplement noted, Sage's stock traded at $21.29 on November 3, 2023.

334. Also on November 7, 2023, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the third quarter ended September 30, 2023, and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed, that contained similar misstatements and omissions as the press release and call. They signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading.

335. As the following excerpt reflects, the Form 10-Q continued to address Auvelity (by referencing AXS-05) in a general way in describing potential competition:

> In August 2022, the FDA approved AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion, an FDA-approved antidepressant affecting norepinephrine and dopamine, for the treatment of MDD in adults.

336. In the press release, Sage announced that the wholesale acquisition cost of zuranolone for PPD was $15,900 for a full 14-day treatment course—well above the $10,000 cost that Sage had

previously guided. The press release also noted that Sage expected the August 2023 reorganization to produce annualized net savings of approximately $240 million, 60% of which related to R&D and $100 million of which related to the workforce reduction.

337. Attending the conference were Greene, Iguchi, Benecchi, Gault, and Kaplowitz, as well as eleven analysts. According to Greene, Sage had not yet determined how to handle the FDA's rejection of zuranolone for MDD, noting "we plan to provide updates when Sage and Biogen have made decisions on the program." In discussing the cost of zuranolone for PPD, Benecchi said "[i]t is within the annual wholesale acquisition range of other commonly prescribed branded medications used to treat brain health disorders," while Greene declined to say whether Sage had plans to change pricing if zuranolone had received FDA approval for MDD.

338. On November 8, 2023, Sage announced its participation in the November 15, 2023 Stifel 2023 Healthcare Conference and November 30, 2023 Piper Sandler 35th Annual Healthcare Conference. At the Stifel conference, Benecchi and Gault promoted SAGE-324 and SAGE-718, while extolling the attributes of zuranolone in treating PPD. At the Piper Sandler conference, which Iguchi and Benecchi attended, Iguchi confirmed that Sage shifted its focus to launching zuranolone for PPD—noting the Company was "putting all our focus there, Biogen as well," and stating that "the investment thesis here is really about a postpartum depression drug with ZURZUVAE." At that conference, Benecchi also continued to promote SAGE-324 and SAGE-718.

339. Capping off the year, on December 14, 2023, Sage issued a press release announcing that Zurzuvae—the branded name for zuranolone, approved to treat PPD—was available in the U.S.

F. Until June 2024, Defendants Continued to Issue Positive Statements on SAGE-718 and SAGE-324 Until Their Clinical Trials Failed

340. On January 8, 2024, Greene, Iguchi, Benecchi, and Chief Scientific Officer Michael Quirk ("Quirk") attended the 42nd Annual J.P. Morgan Healthcare Conference. Greene provided

background on the launch of zuranolone for PPD, while Iguchi said Sage was "working with Biogen and still aligning on" launch metrics to provide the market. Greene also favorably discussed SAGE-718 and SAGE-324, noting Sage had five "clinical studies up and running this year with four top line data readouts" for SAGE-718 and stating, for SAGE-324: "What we saw with KINETIC, as we saw at a 60-milligram dose, we saw significant clinically meaningful and statistically significant change in tremor amplitude . . . ."

341. Before the market opened on February 14, 2024, Sage issued a press release (attached as an exhibit to a Form 8-K filing), and held a conference call with investors and analysts, reporting and discussing financial results for the fourth quarter and full year ended December 31, 2023. Sage also filed its 2023 Annual Report on Form 10-K. The Form 10-K, which Greene and Iguchi signed, contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-K is accurate and non-misleading. As the following excerpt reflects, the Form 10-K continued to address Auvelity (by referencing AXS-05) in a general way in describing potential competition:

> Zuranolone, if approved in the future for the treatment of MDD, may also face competition from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion approved for the treatment of MDD in adults . . . .

342. The press release described zuranolone's launch for the treatment of PPD since late-2023, as well as ongoing clinical trials for SAGE-718 and SAGE-324. Attending the conference call were Greene, Iguchi, Benecchi, Gault, Quirk, and Kaplowitz on behalf of Sage, and 12 analysts. During the call, Gault tried to hedge and downplay expectations about SAGE-718's ongoing studies, claiming "the primary objective of the SURVEYOR study is to understand the magnitude of the cognitive impairment in Huntington's relative to healthy individuals," not "to show statistically significant differences" from "placebo." And Greene and Gault noted that SAGE-324 demonstrated

a statistically significant reduction in essential tremor in the KINETIC study, while the KINETIC2 study sought to determine optimal dosage for chronic administration.

343. Greene also expressed unbridled enthusiasm on SAGE-718's testing, claiming "[w]e really are excited by the progress" and "excited to have readouts for both Huntington's, Parkinson's and Alzheimer's this year." Gault claimed "we will take what we learned from the SURVEYOR study and make a decision about what the proper endpoints should be for DIMENSION," but added: "we have no reason to believe that th[e] endpoint will not be appropriate or sufficient . . . ."

344. Thus, although analysts asked pointed questions regarding the design of ongoing and anticipated clinical studies for SAGE-718 and SAGE-324, Defendants allayed any concerns over the design and administration of the studies—continuing to conceal substantial risks associated with those studies and the performance of the two drugs under development.

345. On March 5, 2024, Iguchi, Benecchi, and Gault participated in the T.D. Cowen 44th Annual Healthcare Conference. Gault made statements similar to those on February 14, 2024, again claiming that an adverse result in one SAGE-718 study might not have relevance to others, stating: "it's absolutely not the case that a positive or negative result in one of these studies is a perfect predictor of what will happen for subsequent studies." She also explained the differences between the DIMENSION and SURVEYOR studies again, including their endpoints and use of the Wechsler Adult Intelligence Scale coding. And when asked if the FDA would "buy into" using the TETRAS scale for SAGE-324's studies, Gault said it is "a good measure to use for signal detection."

346. On March 19, 2024, Greene participated in the Stifel Virtual CNS Days conference. He largely repeated statements that he and other Sage representatives previously made, including that the SURVEYOR study for SAGE-718 "is not powered or designed for statistical significance but rather to show the difference between health[y] Huntington's patients and drug." Ultimately,

Greene was forced to explain the unorthodox study endpoints, and he endeavored—convincingly—to allay concerns regarding those endpoints. For example:

a. The host inquired about Sage's use of the Huntington's Disease Cognitive Assessment Battery, (or HD-CAB), noting "[a]nother company in the space basically got feedback from the FDA that they didn't like this measure only a couple years ago" and asking: "why rely on this scale and why not try to look at something else or get better regulatory alignment ahead of time?" The host even asked: "You think that might not be relevant here?" Greene represented that "[w]e have seen good regulatory flexibility in orphan diseases and particularly something here where there's nothing for people suffering from cognitive issues in Huntington's disease" and "we think we've got a number of primary, secondary endpoint[s] to demonstrate am effect here," later adding: "the regulatory precedence is relevant but our conversations are going well."

b. The host also commented that "there's nothing approved in condition" for Parkinson's and Alzheimer's Diseases, noting "the investment community is accustomed to things like ADAS-Cogs, CDR" and remarking: "The measures you guys [are] using, again, don't really have much precedent." Greener responded: "we're measuring a lot of different cognitive measures at various time points" "because we know there may be some learning effect[s] with these kinds of studies," adding: "we'll see what works well, what doesn't work," and "sit down with regulators to map out what the right Phase 3s look like." According to Greene: "there's no precedent . . . ."

c. As for SAGE-324, the host asked: "from a regulatory perspective, are we comfortable that the end points you're looking at and the way you're adjudicating tremor?" Greene answered: "yes, there's general alignment" and "with these data in hand, we'll have that discussion."

347. On April 17, 2024, Sage issued a premarket press release, filed as an exhibit to Form 8-K, and held a premarket conference call, regarding topline results from the Phase 2 PRECEDENT study of SAGE-718 in treating mild cognitive impairment in Parkinson's Disease. A double-blind,

placebo-controlled study, the study "did not meet its primary endpoint of demonstrating statistically significant difference from baseline in participants treated with once-daily dalzanemdor versus placebo on the Wechsler Adult Intelligence Scale Fourth Edition-IV (WAIS-IV) Coding Test score at Day 42." Additionally, "[a]nalyses did not suggest any meaningful differences versus placebo in the other exploratory endpoints such as SCOPA-Cog." Although results were expected for other Phase 2 studies in Huntington's and Alzheimer's Diseases later that year, the release indicated that, "[b]ased on the data, the Company does not plan any further development of dalzanemdor (SAGE-718) in PD [Parkinson's Disease]."

348. Greene, Gault, and Kaplowitz participated in the premarket conference call, as well as a diminished number of only five analysts. Although both Greene and Gault acknowledged the study's failure to meet primary or other endpoints, Gault hedged, claiming "we believe these results are not necessarily predictive of the results in our other ongoing studies" and adding:

> It is important to remember that although cognitive impairment is common across Parkinson's, Huntington's and Alzheimer's diseases, the underlying pathophysiology and symptomatology of these diseases are very distinct. Further, the dalzanemdor studies differ in terms of indication, patient selection criteria, duration of treatment, sample size and certain endpoints.

349. In response to an analyst question on the endpoints, Greene repeated that message, representing that "the results we've seen here are not necessarily predictive of the results we'll see in Huntington's and Alzheimer's," adding: "the endpoint in the Huntington trials, particularly is very different than the endpoint we saw here." In turn, Gault again claimed "the endpoints are different," explaining that while tests underlying the endpoints "are both measuring cognition, they're doing so in very different ways" in "populations [that] are very different." All told, Greene and Gault claimed the results were not "necessarily predictive" of the other tests four times—another effort designed to allay any lingering (or intensifying) concerns.

350. In response to this adverse news—which suggested that Sage improperly designed the SAGE-718 study, which was doomed to fail—Sage's stock price fell $3.06 per share, or 19.58%, from $15.63 per share on April 16, 2024 to $12.57 per share on April 17, 2024 on elevated trading volume. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
April 16, 2024	$15.22	$15.74	$15.06	$15.63	1,939,500
April 17, 2024	$12.96	$13.42	$10.92	$12.57	4,315,900

351. On April 25, 2024, Sage issued a premarket press release, filed as an exhibit to Form 8-K, announcing financial results for the first quarter ended March 31, 2024, and held an earnings conference call with investors and analysts. Sage also filed a Form 10-Q, which Greene and Iguchi signed and which contained similar misstatements and omissions as the press release and call. They also signed SOX Certifications, representing that the Form 10-Q is accurate and non-misleading. As the following excerpt reflects, the Form 10-Q continued to address Auvelity (by referencing AXS-05) in a general way in describing potential competition:

> Zuranolone, if approved in the future for the treatment of MDD, may also face competition from AXS-05, a combination formulation of an NMDA receptor antagonist, dextromethorphan, with bupropion approved for the treatment of MDD in adults . . . .

352. The press release referenced Sage's April 17, 2024 disclosure that for SAGE-718, the PRECEDENT study did not meet its primary endpoint of statistical significance versus placebo at Day 42, and that Sage "does not plan any further development" of the drug as a potential treatment for Parkinson's Disease. The release, however, outlined the ongoing studies for each of SAGE-718 and SAGE-324.

353. Greene, Iguchi, Benecchi, Gault, Quirk, and Kaplowitz participated in the premarket conference call, which 13 analysts attended. In his opening remarks, Greene again claimed that the PRECEDENT results "are not necessarily predictive of the results in our ongoing studies," repeating

lines he and Gault delivered at the April 17, 2024 conference, including: "It's important to remember that while cognitive impairment is common across Huntington's disease and Alzheimer's disease, the underlying pathophysiology and symptomatology of these diseases are very distinct." In fact, Gault also repeated that line, while making positive representations about other ongoing studies:

> As we said on our call last week, is it is important to remember that these results are not necessarily predictive of the results we may see in our ongoing Huntington's disease and Alzheimer's disease studies, given the very distinct underlying pathophysiology and symptomatology of these diseases. While we're disappointed by the results of the PRECEDENT study, we continue to believe in the potential of dalzanemdor in the other indications we are studying and look forward to the various data readouts anticipated later this year.

354. Gault also again emphasized and tried to "underscore that the primary objective of the SURVEYOR study is to understand the magnitude of the cognitive impairment in HD," reiterating it "is not designed nor powered to show statistically significant differences between [SAGE-718] and placebo." As for SAGE-324, she cited "encouraging data" from the KINETIC study and favorably referenced the ongoing KINETIC2 study. When asked, however, she did not detail the efficacy or safety signals that would warrant moving forward to Phase III studies.

355. An analyst also asked about the primary endpoint in the DIMENSION study (citing the HD-CAB), noting that "another company in the space had trouble getting the FDA on board with that measure"—a concern previously flagged for Greene at the March 19, 2024 Stifel conference. Gault avoided a direct answer, claiming the SURVEYOR study was "designed to provide data to put context around the HD-CAB to help us understand what . . . clinically meaningful change looks like." But that response confused analysts, prompting one to ask "in what way the SURVEYOR data will inform the DIMENSION study?" Gault answered that "scales" in both studies "are largely overlapping" and repeated her last answer about "clinically meaningful change . . . ."

356. Confusion remained, however, and another analyst asked for detail to "understand the difference between the endpoint[s]" for KINETIC and KINETIC2, prompting Gault to confirm that

both "use the same primary endpoint, which is the upper limb extremity score from the TETRAS performance scale," adding: "We are aware . . . [of] regulatory feedback about using the ADL scale associated with TETRAS." But given Gault's credentials, expertise, and experience—and Sage's consistent, positive messaging—the full extent of the implications of Defendants' choice of endpoint remained unclear.

357. On June 11, 2024, Sage issued a press release announcing the results of SAGE-718's Phase 2 SURVEYOR study. The release, filed as an exhibit to Form 8-K, reported that "[t]he study met its primary endpoint demonstrating a statistically significant difference as measured by the [HD-CAB] . . . composite score at baseline between healthy participants and [those] with Huntington's Disease . . . ." The release quoted Gault, who stated "there are no approved treatments for cognitive impairment in HD . . . ." And while reiterating that "[t]he study was **not** designed or powered to demonstrate a statistically significant difference between dalzanemdor [SAGE-718] and placebo" (emphasis in original), the release noted: "There was a small numerical difference observed between dalzanemdor and placebo on the HD-CAB composite score at Day 28."

358. On June 12, 2024, Greene and Gault attended the Goldman Sachs Global Healthcare Conference. In describing SAGE-324 KINETIC study, Gault indicated that "[w]hat we learned . . . is the drug works," "[i]t reduced tremor amplitude," but when patients took that 60-milligram dose in the morning, it wasn't very tolerable." The KINETIC2 study, she explained, requires an evening dose—at 15, 30, or 60 mg—for 12 weeks, but "[t]he primary endpoint remains, the TETRAS performance scale," which examines "tremor amplitude." As on previous occasions, the host asked "what's the rationale behind evaluating the TETRAS subscale item for endpoint, considering completing trials are looking at different endpoints here?" As before, Gault again acknowledged the FDA's general resistance to using TETRAS as an endpoint, but again convincingly defended its use in evaluating SAGE-324:

> [W]e're aware that there has been some regulatory feedback to other sponsors about using the modified ADL. However, when you're trying to learn about how your product works, you want to measure something that is as proximal to its effect as possible. So actually measuring the tremor amplitude is much more proximal than measuring something around activities of daily living down the road.

359. To this, Greene added that if "we sit down with regulators and other endpoints are required, we feel pretty confident that we'll be able to do that as well." And on SAGE-718, Greene and Gault generally recounted the SURVEYOR study results reported on June 11, 2024. The market was, accordingly, left with the positive impression that Defendants understood and appreciated the most effective way to develop the Company's remaining product portfolio.

360. That all changed the following day. On July 24, 2024, Sage issued a press release, filed as an exhibit to Form 8-K, reporting topline results of the Phase 2 KINETIC 2 study of SAGE-324 for the treatment of essential tremor. The release indicated that the study "did not demonstrate a statistically significant dose-response relationship in change from baseline to Day 91 based on the primary endpoint, The Essential Tremor Rating Assessment Scale (TETRAS) Performance Subscale (PS) Item 4 (upper limb) total score, in participants with ET [essential tremor]." Additionally, "there were no statistically significant differences demonstrated for any dose of SAGE-324 versus placebo in the change from baseline to Day 91 on the TETRAS PS Item 4 Total Score or the TETRAS Activities of Daily Living (ADL) Composite Score." As the release indicated, "[g]iven these results, Sage and Biogen will close the ongoing open label safety study of SAGE-324 in ET and do not plan to conduct further clinical development of SAGE-324 in ET." The release indicated, however, that Sage and Biogen were "evaluating next steps, if any, for other potential indications."

361. In response to this news, Sage's stock price fell $2.70 per share, or 20.64%, to close at $10.38 per share on July 24, 2024—down from a closing price of $13.08 per share on the prior trading day, July 23, 2024, on unusually high trading volume. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
July 23, 2024	$12.51	$13.47	$12.40	$13.08	934,300
July 24, 2024	$10.08	$11.09	$9.81	$10.38	2,619,800

362. The stock price continued to slide thereafter, as the fallout from the exposure of the Class Period misrepresentations and omissions continued to impact the Company. Additional stock price declines following the Class Period were a natural consequence of Class Period developments, as alleged further herein.

VI. POST-CLASS PERIOD DEVELOPMENTS AND DISCLOSURES EXPOSE THE FRAUD, REQUIRING ANOTHER WORKFORCE REDUCTION AND RESTRUCTURING—CAUSING SIGNIFICANT STOCK PRICE DECLINES

363. In the wake of adverse news regarding SAGE-324's latest study, Sage was forced to implement another round of workforce reductions and corporate restructuring as it experienced other setbacks. Ultimately, Sage substantially reorganized its operations for the purpose of focusing on commercializing Zurzuvae, ceasing efforts to pursue an indication for MDD and even discontinuing the sale of Zulresso.

364. For example, on September 26, 2024, Sage announced that Biogen had terminated the collaboration and license agreement for the SAGE-324 program. Accordingly, effective February 17, 2025, Sage would obtain full ownership of the SAGE-324 asset. Within a month, Sage reported plans to effect another wide-scale corporate restructuring akin to the August 2023 reorganization.

365. On October 17, 2024, Sage announced a "strategic reorganization" of business operations to focus on the promotion of zuranolone (marketed as Zurzuvae) to treat PPD. The reorganization required terminating approximately 33% of the Company's workforce—involving 165 employees, and about 55% of R&D employees—and a management shakeup that would result in Iguchi's ouster as CFO, as well as the departure of four other high-level executives.

366. Then, on October 29, 2024, Sage disclosed that it and Biogen "will not pursue further development of zuranolone as a treatment for MDD in the U.S. based on the significant new

investment and time we expect would be needed to conduct additional studies." This announcement marked the end of Sage's plans to pursue FDA approval of zuranolone for the treatment of MDD—only three months after the July 31, 2024 Form 10-Q (for the second quarter ended June 30, 2024), the last filing in which Sage described AXS-05 as a potential competitor. But the October 29 press release disclosed other troubling news, based on developments occurring during the Class Period, that would reshape the Company.

367. On that date, Sage also reported that because the SAGE-718 LIGHTWAVE study "did not demonstrate a statistically significant difference from baseline" versus placebo at Day 84, "the primary endpoint," Sage "does not plan further clinical development of dalzanemdor in AD [Alzheimer's]." This represented the Company's loss of its third potential drug candidate, following a failure to obtain FDA approval for zuranolone in MDD and the discontinuation of development efforts for SAGE-324.

368. Additionally, also on October 29, 2024, Sage disclosed "plans to sunset" Zulresso "as a part of its strategic shift" to focus on commercializing Zurzuvae, confirming that Zulresso would be available only until December 31, 2024.

369. This news sparked a 24% decline in Sage's stock price on October 30, 2024, when the price closed at $6.44 per share on volume of over 2.3 million shares traded—down from $8.48 per share the previous day. News of these developments caused the stock price to slide for another three trading days. The following chart is illustrative:

Date	Open	High	Low	Close	Volume
Oct. 29, 2024	$8.53	$8.70	$8.34	$8.48	861,300
Oct. 30, 2024	$7.69	$7.97	$6.20	$6.44	2,312,100
Oct. 31, 2024	$6.39	$6.59	$5.91	$6.08	1,381,900
Nov. 1, 2024	$6.09	$6.16	$5.84	$6.05	1,060,700
Nov. 4, 2024	$5.92	$6.12	$5.80	$5.81	735,600

370. These post-Class Period developments and disclosures confirmed the significant harm to investors resulting from Defendants' fraudulent scheme, detailed herein.

VII. ITEMS 303 AND 105 OF SEC REGULATION S-K ALSO REQUIRED THE DISCLOSURE OF MATERIAL INFORMATION

371. As detailed below, the SEC has adopted two regulations—Items 303 and 105 of SEC Regulation S-K—that require public companies to describe in their SEC filings known uncertainties (Item 303) and the most material factors that rendered an investment speculative or risky (Item 105). Although Sage addressed business and industry uncertainties and risks in Class Period SEC filings, those filings did not disclose all facts necessary to provide a non-misleading, complete, or accurate representation of the uncertainties and risks facing zuranolone, SAGE-718, or SAGE-324—or, more generally, the Company itself.

A. Item 303 Required Disclosure of Additional Information to Render Non-Misleading Statements About Material Uncertainties that Sage Faced

372. Item 303(a)(3)(ii) of SEC Regulation S-K, 17 C.F.R. §229.303(a)(3)(ii), requires an issuer to "[d]escribe any known trends or uncertainties that have had or that the registrant reasonably expects will have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." In May 1989, the SEC issued an interpretive release regarding Item 303 ("1989 Interpretive Release"), stating, in pertinent part, as follows:

> Required disclosure is based on *currently known trends, events, and uncertainties that are reasonably expected to have material effects*, such as: A reduction in the registrant's product prices; erosion in the registrant's market share; changes in insurance coverage; or the likely non-renewal of a material contract.
>
> * * *
>
> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.

373. The 1989 Interpretive Release set forth the following test to determine if disclosure under Item 303(a) is required:

> Where a trend, demand, commitment, event or uncertainty is known, management must make two assessments:

> (1) Is the known trend, demand, commitment, event or uncertainty likely to come to fruition? If management determines that it is not reasonably likely to occur, no disclosure is required.
>
> (2) If management cannot make that determination, it must evaluate objectively the consequences of the known trend, demand, commitment, event or uncertainty, on the assumption that it will come to fruition. Disclosure is then required unless management determines that a material effect on the registrant's financial condition or results of operations is not reasonably likely to occur.

374. Additionally, the SEC published interpretive guidance, effective December 29, 2003, regarding the disclosure known as Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, which is required by Item 303. In that guidance, the SEC advised that "companies must identify and disclose known trends, events, demands, commitments and uncertainties that are reasonably likely to have a material effect on financial condition or operating performance," citing the 1989 Interpretive Release and quoting, in footnote 6, the text of the 1989 Interpretive Release:

> MD&A mandates disclosure of specified forward-looking information, and specifies its own standards for disclosure—*i.e.*, reasonably likely to have a material effect. The specific standard governs the circumstances in which Item 303 requires disclosure.

375. During the Class Period, Sage described information about each of its three main drug candidates, and detailed particular uncertainties facing its business, in its quarterly and annual SEC filings. These descriptions included detailed information on the structure and results of clinical trials and related information relevant to the Company's plans to develop zuranolone, SAGE-718, and SAGE-324. Additionally, Sage generally described competition facing the Company in its Forms 10-Q and 10-K, and when it was pursuing FDA approval of zuranolone for MDD, those SEC filings described AXS-05 as a potential competitor.

376. In contravention of Item 303, however, these filings failed to adequately detail some of the most material uncertainties facing the Company during the Class Period, instead providing only a partial—and thus materially misleading—account. For example, the Company's SEC filings:

a. Described zuranolone's clinical trials in MDD, but failed to disclose internally known and material uncertainties surrounding Sage's failure or inability to design trials, consistent with FDA and industry guidance, capable of producing statistically significant evidence of long-term durability in treating MDD.

b. Identified AXS-05 as a competitor to zuranolone in the treatment of MDD, but failed to appropriately disclose details on clinical studies relating to that competing drug, or material implications for zuranolone's FDA approval prospects, all of which posed known uncertainties to the Company's development of zuranolone for MDD—the most significant market opportunity.

c. Described clinical trials for SAGE-718 and SAGE-324, but failed to disclose internally known and material uncertainties surrounding Sage's design and structure of those trials, including the primary endpoints chosen, that substantially increased the risk of negative results.

377. The partial disclosure of information about these issues and uncertainties triggered an obligation to disclose additional information necessary to render those statements complete and non-misleading, consistent with Item 303's express disclosure obligations and SEC guidance.

B. Item 105 Required Disclosure of Additional Information to Render Non-Misleading Statements About Sage's Most Material Risks

378. Item 105(a) of SEC Regulation S-K, 17 C.F.R. §229.105(a)—formerly, Item 503, 17 C.F.R. §229.503(c)—requires an issuer to "provide under the caption 'Risk Factors' a discussion of the material factors that make an investment in the [securities] . . . speculative or risky." Item 105(a) specifically cautions that "[t]he presentation of risks that could apply generically to any registrant . . . is discouraged," while Item 105(b) directs the issuer to "[e]xplain how each risk affects the registrant or the securities being offered." Item 105 neither imposes nor implicates a knowledge requirement.

379. During the Class Period, Sage described in its quarterly and annual SEC filings some of the most prominent risks it faced. These risks involved potential issues affecting the Company's

clinical trials, drug development, FDA approval of late-stage drugs, and operations generally. The Company also disclosed, in the most general way, the risks associated with AXS-05 as a competitor.

380. As alleged herein, however, Sage failed to adequately describe or update in its SEC filings its most material risks. These risks included internally known deficiencies in the design and structure of clinical trials, as well as material deficiencies in the nature, degree, quality, and extent of the study data Sage had developed for each of zuranolone, SAGE-718, and SAGE-324.

381. These risks also pertained to Auvelity, whose FDA approval jeopardized zuranolone's prospects for approval as a treatment for MDD—Sage's largest and most valuable potential market. Instead, Sage's description of AXS-05 remained substantively the same throughout the Class Period, except for minor timing developments pertaining to AXS-05's NDA that did not reveal information on the pronounced—and perhaps most pronounced—risks facing the Company. As set forth herein, the innocuous, benign disclosures regarding AXS-05, which the Class Period Forms 10-Q and 10-K included, failed to adequately detail these material risks, but rather minimized them by implication.

382. The partial disclosure of information about these risks triggered an obligation to disclose additional information necessary to render those statements complete and non-misleading, consistent with Item 105's express disclosure obligations and SEC guidance.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

383. Defendants were responsible for, and had the authority to, disseminate information during the Class Period regarding Sage's operations, and the Individual Defendants regularly spoke about these and other issues, with the authority to do so, on behalf of the Company. At all relevant times, the Individual Defendants spoke about issues they would logically have reason to know about or otherwise had access to nonpublic and internal information about those issues that would enable them to speak in detail and intelligently about those issues. These issues involved the Company's development of zuranolone, SAGE-718, and SAGE-324, as well as communications with the FDA.

384. Specifically, during the Class Period, Defendants knew that Sage's three main drugs under development faced significant obstacles to demonstrating statistical significance in ongoing clinical trials, justifying further study, or—in zuranolone's case—achieving FDA approval. During the Class Period, Defendants consistently monitored and evaluated the performance and study results of competing drugs, and, therefore, understood and appreciated the discrete barriers to further testing and development. Nevertheless, Defendants led the market to believe that they had appropriately designed studies for each of Sage's main three drug candidates—studies that were sufficient to show statistical significance, efficacy, and durability, consistent with FDA guidance and otherwise.

385. Additionally, Defendants purposely provided partial information on their interactions with the FDA, knowing that the market could not independently verify the nature and substance of those communications. The FDA, by custom and practice, does not typically, if ever, publicly reveal information about its interactions with pharmaceutical developers and manufacturers, nor does the FDA publicly reveal the substance of Complete Response Letters or reasons for denying approval of an NDA. Throughout the Class Period, Defendants exploited the FDA's policy of nondisclosure, providing unilateral and often biased guidance to the market regarding the Company's FDA-related communications, dealings, insight, and relationship. All of this skewed the perception of investors and analysts, who had no independent or other source of, or access to, information regarding Sage's interactions with the FDA.

386. Despite their intimate knowledge of these matters, the Individual Defendants—and Sage itself—authorized, prepared, and issued false and misleading statements regarding these issues. During the Class Period, Defendants controlled the dissemination of public information regarding the Company. They authorized, prepared and issued statements to the media, analysts, and investors, orally and in writing. These modes of communication included Sage press releases, SEC filings, and statements in analyst reports, the news media, and conference calls. The Individual Defendants

reviewed, approved, ratified, and otherwise furnished information and language for inclusion in public statements by or on behalf of the Company during the Class Period.

IX. LOSS CAUSATION AND ECONOMIC LOSS

387. As detailed herein, Defendants engaged in a scheme to deceive the market and a reckless, if not purposeful, course of conduct which artificially inflated the price of Sage securities and operated as a fraud or deceit on Class Period purchasers, including Plaintiffs.

388. As alleged herein, when these misrepresentations and this fraudulent conduct were exposed and became apparent to the market, the trading price of the Company's common stock fell precipitously as this inflation was removed. Accordingly, as a result of their Class Period purchases, Class members suffered economic loss, *i.e.*, damages, under the federal securities laws.

389. Accordingly, Defendants' wrongful conduct directly and proximately caused losses and thus damages suffered by Class members, including Plaintiffs.

X. A PRESUMPTION OF RELIANCE APPLIES

390. A presumption of reliance applies under *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the claims alleged are predicated upon omissions of material fact for which there was a duty to disclose, as alleged herein.

391. Additionally, a presumption of reliance applies under the fraud-on-the-market theory of reliance because the market for Sage common stock was efficient during the Class Period:

a. Sage common stock was listed and actively traded on the NASDAQ, an efficient and electronic stock market that reflected the prompt incorporation and reflection of information, throughout the Class Period;

b. Sage common stock traded at volumes during the Class Period that reflected the impact of available information and the trading price reacted promptly to publicly available news and information;

c. Sage filed periodic public reports with the SEC and regularly communicated with analysts and investors using established market communication mechanisms, including press releases; and

d. Securities analysts and investors followed Sage and issued reports on its prospects and performance, and information on Sage entered the marketplace and was reflected in the trading price of its common stock.

392. As a result of the foregoing, the market for Sage common stock promptly digested relevant information from publicly available sources and its trading price reflected such information. Under these circumstances, all purchasers of such securities during the Class Period suffered similar injury by purchasing at artificially inflated prices and a presumption of reliance applies.

XI. NO PROTECTION INSULATES DEFENDANTS FROM LIABILITY

393. Neither the safe harbor for forward-looking statements under certain circumstances, nor the bespeaks caution doctrine, applies to any of the materially false and misleading statements or omissions alleged herein.

394. *First*, the materially false and misleading statements and omissions relate to historical facts or existing conditions, and omissions are not protected by the statutory safe harbor. Such false or misleading statements are not forward-looking because they: (a) relate to historical or current fact; (b) implicate existing conditions; and (c) do not contain projections of future performance or future objectives. If any statements might be construed to touch on future intent, they are mixed statements of present fact and future intent and are not entitled to safe harbor protection with respect to the part that refers to the present.

395. *Second*, any purported cautionary language was not meaningful and therefore was ineffectual because any risks warned of had already transpired and the language was boilerplate, was

not specifically tailored to the risks at issue, did not change as risks evolved or conditions changed, and did not mention important factors of similar significance to those actually realized.

396. *Third*, Defendants are liable for any forward-looking statement identified as such (or otherwise) because they knew the statement was false or misleading when made. Additionally, any such statement was authorized or approved by a Defendant or executive officer who could bind any of Defendants and who knew the statement was false or misleading when made. All such false or misleading statements are accordingly attributable to Sage and other Defendants, whether identified as forward-looking or otherwise.

XII. CLASS ACTION ALLEGATIONS

397. This action is brought as a class action under Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of all persons and entities who purchased or otherwise acquired the securities of Sage during the Class Period (collectively, the "Class"). Excluded from the Class are Defendants and their families; officers, directors and affiliates of Defendants and members of their immediate families at all relevant times; the legal representatives, heirs, successors or assigns of any of the foregoing; and any entity in which any Defendant has or had a controlling interest.

398. The members of the Class are so numerous that joinder is impracticable. Throughout the Class Period, Sage common stock was actively traded on the NASDAQ and millions of shares were publicly traded. While the exact number of Class members is unknown at this time and can only be ascertained through discovery, there are likely hundreds, if not thousands, of members in the Class. Class members may be identified from records maintained by Sage or its transfer agent and may be notified of the pendency of this action by mail using a form of notice customarily used in securities class actions.

399. Common questions of law and fact exist as to all Class members that predominate over any questions solely affecting individual Class members, including: (a) whether Defendants

violated the Exchange Act, as alleged; (b) whether Defendants misrepresented or omitted material information during the Class Period in violation of the Exchange Act; and (c) whether and to what extent Class members have sustained damages, as well as the proper measure of damages.

400. The claims asserted herein and brought by Plaintiffs are typical of the claims of the Class as all Class members were similarly affected by Defendants' violation of the federal securities laws. Plaintiffs will fairly and adequately protect the interests of Class members and have retained counsel who are competent and experienced in securities class actions.

401. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it exceedingly difficult, if not impossible and impracticable, for Class members to individually redress the wrongs alleged. There will be no difficulty in managing this action as a class action.

XIII. CLAIMS

A. COUNT ONE: Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

402. Each and every allegation set forth above is repeated, incorporated, and realleged as if fully set forth below.

403. This claim is brought against Defendants pursuant to Section 10(b) of the Exchange Act, 15 U.S.C. §78j(b), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5. During the Class Period, Defendants knowingly or recklessly prepared, issued, or approved false and materially misleading statements without regard for the truth, and in doing so, they:

a. employed devices, schemes, and artifices to defraud;

b. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or

c. engaged in acts, practices, and a course of business that operated as a fraud or deceit upon all Class members who purchased common stock during the Class Period.

404. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements they issued, approved, or otherwise disseminated were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws.

405. Additionally, as set forth elsewhere herein, Defendants participated in the fraudulent scheme alleged herein by virtue of their receipt of information reflecting the true facts, their control over the allegedly materially false and misleading statements and omissions, and their access to non-public information. Further, as detailed above, Defendants had a duty to disclose the material facts described herein and violated their duty to do so.

406. All Class members, including Plaintiffs, have suffered damages because, in reliance on the integrity of the market, they paid artificially inflated prices for Sage common stock. They would not have purchased the securities at the prices they paid, or at all, had they been aware that market prices had been artificially and falsely inflated by Defendants' false and materially misleading statements.

407. As a direct and proximate result of Defendants' misconduct, all Class members, including Plaintiffs, suffered damages in connection with their Class Period purchases of Sage securities.

B. COUNT TWO: Violation of Section 20(a) of the Exchange Act Against the Individual Defendants

408. Each and every allegation set forth above is repeated, incorporated, and realleged as if fully set forth below.

409. This claim is brought against the Individual Defendants pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. §78t(a). During the Class Period, the Individual Defendants controlled a primary violator of the federal securities laws, Sage.

410. By virtue of their high-level positions as executives and/or directors, the Individual Defendants were privy to, and monitored, confidential and proprietary information about Sage, its business, operations, performance, and future prospects. They had access to nonpublic information about Sage's business, operations, performance, and future prospects via access to internal corporate documents, information, and personnel, and controlled and otherwise dictated the mode and method of communicating with the investing public.

411. The Individual Defendants were controlling persons of Sage within the meaning of Section 20(a), as alleged herein. By virtue of their high-level positions, their participation in and awareness of the Company's day-to-day operations and finances, and/or knowledge of statements by the Company and others that were disseminated to the investing public, the Individual Defendants had the power and authority to influence and control, directly or indirectly, the day-to-day decision-making of the Company, including the content and dissemination of the actionable statements and omissions. And the Individual Defendants exercised this influence and control.

412. To the extent necessary, the Individual Defendants were culpable participants in the fraud alleged herein.

413. As a result, the Individual Defendants are liable as control persons under Section 20(a). As a direct and proximate result of such misconduct, all Class members, including Plaintiffs, suffered damages in connection with their Class Period purchases of Sage securities.

XIV. PRAYER FOR RELIEF

WHEREFORE, based on the foregoing and all proceedings herein, the Court is respectfully requested to enter judgment against Defendants as follows:

A. Determining that this action is properly brought as a class action and certifying the Class accordingly, designating Plaintiffs as Class representatives, and appointing Robbins Geller Rudman & Dowd LLP and Abraham, Fruchter & Twersky, LLP as Class Counsel;

B. Awarding compensatory damages to the Class, including Plaintiffs, against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, together with prejudgment interest thereon;

C. Awarding to the Class, including Plaintiffs, reasonable costs and expenses incurred in this action, including, but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and

D. Granting such other, further and/or different relief as the Court deems just and proper.

XV. JURY TRIAL DEMAND

A trial by jury is hereby demanded.

DATED: March 3, 2025

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